UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, and COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v. 20 CV 706 (DLC)

MARTIN SHKRELI, et al.,

Defendants.

New York, N.Y.
December 16, 2021
9:30 a.m.

Before:

HON. DENISE COTE,
District Judge

APPEARANCES

FEDERAL TRADE COMMISSION
BY: MARKUS H. MEIER
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SARAH FEHM STEWART
SEAN McCONNELL
J. MANLY PARKS

(Case called)

THE COURT: Good morning, everyone.

The witness can retake the witness stand.

MR. MEIER: Your Honor, if I may, we have a few preliminary matters, if we can take those up.

THE COURT: Sure.

MR. MEIER: Thank you, your Honor. The first thing I'd like to do is simply introduce the paralegal who will be comparably helping us today, Bryce Tuttle. Now you have met all three of our crack assistants that are making this work for us today. Thank you.

THE COURT: Sir, you can come up and take the witness stand.

MR. MEIER: The first item, your Honor, is a designation of the transcripts of a witness named Ramachandra from RL Fine. It's Government Exhibit 9058. There are no changes from the designations that had been admitted in October, and it's my understanding that we have agreement from defendants on the admission of this.

THE COURT: Any objection to receipt of GX-9058?

MR. RUDOWITZ: Your Honor, no objection.

THE COURT: Received.

(Government Exhibit 9058 received in evidence)

MR. MEIER: The next one, your Honor, is Government Exhibit 9059. 9059, your Honor, is the designation of the

transcript of a witness named Eric Sredzinski from a company named Avella. Again, there are no changes from the designations that we submitted in October, and it's my understanding that defendants do not object.

THE COURT: Any objections?

MR. RUDOWITZ: No objection.

THE COURT: 9059 is received.

(Government Exhibit 9059 received in evidence)

MR. MEIER: The next one, your Honor, is Government Exhibit 9060. It's the deposition designations of a witness named Christopher Lau from Vyera. And there have been some changes, as indicated on the first page. So we have withdrawn certain items as indicated. Again, it's my understanding defendants do not object, but I will let them speak for themselves.

THE COURT: Any objection?

MR. RUDOWITZ: No objection, your Honor.

THE COURT: Government Exhibit 9060 is received.

(Government Exhibit 9060 received in evidence)

MR. MEIER: Your Honor, the next one is Government Exhibit 9061. These are the deposition designations of Lucas Schulz from the University of Wisconsin Hospitals and Clinics. There has one modification here, as indicated on the cover that we submitted back in October. It's my understanding that defendants do not object.

THE COURT: Any objection?

MR. RUDOWITZ: No objection, your Honor.

THE COURT: Government Exhibit 9061 is received.

(Government Exhibit 9061 received in evidence)

MR. MEIER: The next one, your Honor, is Government Exhibit 9062. It's the designations of a witness named Kevin Wessel from CVS Capital. Again, it's my understanding that defendants do not object.

THE COURT: Any objection to GX-9062?

MR. RUDOWITZ: No objection, your Honor.

THE COURT: Received.

(Government Exhibit 9062 received in evidence)

MR. MEIER: Your Honor, this is Government Exhibit 5005. There is a cover letter in the front. I'll explain in a moment. It is the investigational hearing transcript of a witness named Michael Smith from Vyera.

The issue here, your Honor, why we put a cover letter on it is, we wanted to let your Honor know that in discussions with the defendants, it is my understanding defendants wanted us to put the entire transcript in without any highlighting on it. But in our October submission we highlighted the relevant passages from this. I'm not really sure the origin of why we couldn't just submit the highlighted version. Maybe Mr. Rudowitz would like to speak to that.

THE COURT: I have the highlighted version with the

pretrial order.

MR. MEIER: You do, your Honor.

MR. RUDOWITZ: Your Honor, we object to the highlighted designations of the investigational hearing transcripts as they are not Rule 32 depositions. But we do not object to the admission of the investigational hearing transcript as a whole, subject to your Honor's rulings.

THE COURT: Thank you, counsel.

I obviously wrote on the evidentiary objection that was made for the offer of testimony given during the investigational hearings, so I'm not quite sure how to understand your objection. You're withdrawing those objections so long as the entire transcript is offered?

MR. RUDOWITZ: That is correct, your Honor. We understand your Court's ruling to allow in the investigational hearing transcripts as an exception to hearsay.

THE COURT: No. As designated. There were passages designated with the pretrial order. There was an objection made. I ruled on the objection, understanding it was in the context of designated portions. So now I am trying to understand what the defendant's position is.

You no longer object at all to the receipt of the testimony of Mr. Smith at the investigational hearing, so long as all of the testimony comes in?

MR. POLLACK: Your Honor, it appears that we were

under a misapprehension of your Honor's order, which was that we interpreted it to be that the investigational hearing transcripts were not depositions under Rule 32(a), but your Honor had ruled that they could be admissible under Rule 802(d) as party statements by Vyera employees, in which case, under that ruling, they would be admissible as a whole, but not as designated testimony.

We are not withdrawing our objection. We are simply saying that we, subject to how we understood your Honor to have ruled, that in that case they are indeed 802(d) statements that your Honor has ruled that they would be admissible as any other 802(d) document, but not as a deposition.

Because an investigational hearing is not a deposition. Our client had no notice of it. He was not there. Would not have an opportunity to cross-examine at that hearing.

That is our position.

THE COURT: Thank you. Of course I ruled on the general legal issue because I understood that was the dispute between the parties. The defendant at that time only had notice that the plaintiffs wished to offer certain designated material. There could be multiple bases for objections to any passage in testimony given at a hearing or in a deposition.

You are not withdrawing your objection as to the single legal issue as to whether or not Mr. Smith's testimony as an agent of the company is admissible. But you have no

other objection to any of the designated portions that the plaintiffs wanted in and, indeed, you want in the entire transcript.

MR. POLLACK: Your Honor, just to clarify, not only did plaintiffs seek to designate this testimony, they put it on their exhibit list as an exhibit. That was what was before your Honor at the hearing. We did not counterdesignate or object to their designations because we viewed them as improper when made, because the document was not a 32(a) deposition to which designations could have been properly made.

Having received your Honor's ruling on 802(d), we understood the entirety of the document to then constitute a party admission. We don't agree with that, but we accept the Court's ruling, respectfully. That's why our position was that the document can come in as a whole, but we objected to the highlighted portions because the highlighted portions would, in effect, be a designation.

THE COURT: I think the record is clear enough with respect to the defendant's position.

MR. POLLACK: Thank you, your Honor.

THE COURT: I don't think I need to conduct further colloquy to get that position stated on the record.

Do you agree, Mr. Meier?

MR. MEIER: Yes, your Honor.

THE COURT: Thank you.

MR. MEIER: I have another investigational hearing transcript. We have marked it as Government Exhibit 5013.

THE COURT: I'm sorry.

GX-5005 is received.

(Government Exhibit 5005 received in evidence)

THE COURT: Any objection to receipt of GX-5033?

MR. POLLACK: Your Honor, it's the same issue, same objection. I don't believe the Court needs or wants me to right the issue.

MR. MEIER: It's Government Exhibit 5013.

THE COURT: Thank you. 5013.

MR. MEIER: It's the investigational hearing transcript of Nancy Retzlaff from Vyera.

THE COURT: The defendant wants to maintain its original objection about the admissibility of any portion of Ms. Retzlaff's hearing transcript. But in the event any of it comes in, it wishes all of it to come in. Do I understand that correctly?

MR. POLLACK: Yes, you do, your Honor.

THE COURT: Thank you.

GX-5013 is received.

(Government Exhibit 5013 received in evidence)

MR. MEIER: Again, just for the record, as we have pointed out in our cover letter, highlighted versions are available to the Court from the October filing, to the extent

that that's useful to the Court.

The last one I have, your Honor, is Government Exhibit 9002. 9002 is a second list of exhibits to be admitted at trial. My understanding is that we have agreement with the defendants on the admission of these exhibits, which do include a few defendant's exhibits and a number of government exhibits.

THE COURT: Any objection to the receipt of Government Exhibit 9002 and the exhibits listed within it?

MS. STEWART: No objection, your Honor.

THE COURT: Thank you so much. Government Exhibit 9002 and the exhibits listed within it are received.

(Government Exhibit 9002 received in evidence)

THE COURT: Anything further, Mr. Meier?

MR. MEIER: One last point, your Honor. My colleague, Mr. Perlman will be handling the examination of Mr. Della Fera for the government, and we took his declaration off the stand, so we need to give it back to him.

MR. PERLMAN: This also has DX-556, which was the exhibit that defendant showed Mr. Della Fera.

THE COURT: Mr. Della Fera, I remind you you are still under oath.

Cross-examination may resume.

MR. POLLACK: Thank you, your Honor.

FRANK DELLA FERA, resumed.

CROSS-EXAMINATION (cont'd)

BY MR. POLLACK:

Q. Mr. Della Fera, yesterday I erroneously starting off by wishing you a good morning. Today I can do that correctly. Good morning, sir.

A. Good morning.

Q. How are you?

A. Good.

Q. Thank you for being back here today to continue the examination.

I'd like to pick up where we left off yesterday. I have a couple of just clarifying questions for you on a couple of points we touched upon before I move on to my next topic.

One of the things we discussed was the fact that your company, Fera, had entered into two separate agreements with API, company number 1. A confidentiality and exclusivity agreement in 2016, correct?

A. Yes.

Q. Followed then by a supply agreement two years later in 2018, correct?

A. Yes.

Q. Now, the supply agreement, if I'm correct, replaced and superseded the confidentiality agreement, correct?

A. I believe so.

Q. Why did your company, Fera, enter into a supply agreement in 2018 when the confidentiality exclusivity agreement had a

five-year term?
A. I think it was just additional details that we needed to put into our agreement between the two parties, and we both agreed to do it.
Q. It was just a more formalized agreement then?
A. Pardon?
Q. Just a more formalized agreement in that case?
A. Yes.
Q. Thank you.

I also want to just attach a date to an event we discussed. You had mentioned that early on in your evaluation of whether to pursue a generic Daraprim product, Fera reached out to an API supplier called Fukuzyu, correct?
A. Yes.
Q. Now, that contact came, I believe you have previously testified, either late in 2016 or early 2017, is that right?
A. I don't remember the dates.
Q. You don't recall. OK. That's an important date for me. If we showed you your deposition, would that perhaps refresh your recollection on the point?
A. Yes.

MR. POLLACK: Justin could you pull up Mr. Della Fera's deposition at page 42 and highlight lines 12 to 20, please. May need a bit more than that. I'm sorry. Let's take it all the way down to -- that's where. That was actually

perfect.

Q. Mr. Della Fera, take a moment to read that and let me know if that refreshes your recollection.

I had misspoken earlier. Go ahead.

A. I'm listening.

Q. Does that refresh your recollection?

A. Yes.

Q. I said '16, '17. In fact was it in fact late '15, early '16 when someone from your company reached out to Fukuzyu?

A. Correct.

Q. In fact it was prior to March 2016, correct?

A. Yes.

Q. In any event, right?

There was some discussion about the fact that your company then later reached out to Fukuzyu a second time, correct?

A. Yes.

Q. Based upon your written testimony, I understand that to have happened -- that one was late 2017, early 2018, correct?

A. If you could get something that would refresh my memory, it would be helpful.

Q. Sure.

MR. POLLACK: Justin, could we pull up Mr. Della Fera's affidavit, please. Can we direct him to page 8, paragraph 28.

A. Your question is?
Q. Sure. My question is, does that refresh your recollection that the second time that Fera reached out to Fukuzyu was in late 2017, early 2018?
A. Yes.
Q. So approximately one year after its first contact?
A. Yes.
Q. At that point in time API company number 1, from what you told me, had already produced its initial batches of pyrimethamine API in October of 2017, correct?
A. Yes.
Q. And the reason Fera reached out to Fukuzyu in late 2017, early 2018 was to buy a sample of API pyrimethamine to use as a reference test against API company number 1's pyrimethamine, correct?
A. Yes.
Q. What is a reference test?
A. A comparative.
Q. When you say a comparative, what is a comparative?
A. Comparing one manufacturer's product to the product that we were producing.
Q. Why would a company such as yours want to undertake that comparison?
A. We are always looking to ensure that we have the right molecule before we proceed.

Q. Finally, yesterday we discussed the request by another pharmaceutical company named Teva. Am I pronouncing it right? Is it Teva or Teva?

A. Either way works.

Q. We discussed a request by Teva to purchase API from Fera. He told me he basically gave them a price that they couldn't accept because you didn't want to deal with them.

What did you mean by that, you didn't want to deal with Teva?

A. I had been in the business a long time and it's just something that I'm not comfortable doing business with him. They have always been my competitor.

Q. So then you didn't want to sell pyrimethamine API to Teva because it's your competitor?

A. It's the largest generic drug company in the world, and, yes, I don't want to deal with the largest player against my product.

Q. Was that a yes to my question, that you didn't want to sell pyrimethamine API to Teva because they compete with you?

A. I have a longstanding competition --

Q. It's a yes or no, Mr. Della Fera.

A. I said yes before.

Q. Thank you.

Now I want to switch away from Fera's API activities and talk about its efforts to purchase reference listed drugs,

which we also refer to in the industry as RLD, is that right?
A. Yes.
Q. If I use the word RLD, you will know what I'm referring to?
A. Yes.
Q. Very good.
If I understand your testimony correctly, Fera started the process of sourcing RLD in 2016, is that correct?
A. Correct.
Q. Can you briefly explain to us who aren't intimately involved in the pharmaceutical industry why a generic manufacturer such as Fera requires RLD.
A. Part of the requirement from the FDA is to show equivalence, bioequivalence, to the referenced listed drug when you produce a generic product.
Q. Am I correct that the FDA has a five times requirement for RLD?
A. Yes.
Q. Do you know how long that five times requirement has been in place?
A. No.
Q. Was that five times requirement in place in 2015? Do you know?
A. Yes.
Q. Has it been in place since 2015 through the present?
A. Yes.

Q. Were you aware of that five times requirement in 2015?
A. Yes.
Q. Am I correct that in December of 2016, Fera was presented with the opportunity to purchase Daraprim through a company called Tanner Pharma Group?
A. Discussions were with Tanner for a long period of time.
Q. Did Tanner make an offer to Fera to sell it Daraprim in December 2016, right?
A. We were in discussions, yes.
Q. Do you recall what Tanner offered Fera in December of 2016?
A. What they offered is a requirement of a prepayment of over a million dollars without proof or evidence that they had a product.
THE COURT: Mr. Della Fera, I am going to ask you to move that mic down under your chin. Thanks.
Q. The Tanner offer was to sell Fera either a 100-count bottle of Daraprim for $101,328.41 per bottle or a 30-count bottle for $69,033.41 per bottle?
A. I don't recall any of these details.
Q. Is there a document that would refresh your recollection on it, Mr. Della Fera?
A. I'm not aware of a document, unless you have one.
Q. Let me ask you this way. Did your company respond to a civil investigative demand by the FTC in this case?
A. Yes.

Q. If I understand correctly, I believe Ms. McDougal completed these responses, correct?
A. Yes.
Q. You reviewed them before they went out?
A. Yes.
Q. Did you believe them to be accurate when they went out?
A. Yes.
MR. POLLACK: Justin, could we pull up DX-281, please.
Q. Mr. Della Fera, I've put in front of you Exhibit DX-281. Do you recognize this as Fera's response to the FTC's civil investigative demand?
A. Could I have it enlarged, whatever you want me to read.
Q. I'm asking you first, do you recognize it as the response to a civil investigative demand? And then I'll direct you to language in it.
A. No.
Q. You haven't seen this document before?
A. No. You asked me if I recognize it. No.
MR. POLLACK: Take it down, please.
Q. In December of 2016, when Tanner came to Fera, did Fera take it up on its offer to sell it RLD Daraprim?
A. We were in discussions with Tanner, that I'm aware of. I wasn't dealing with it. My colleagues were handling that.
Q. Who was handling it for Fera?
A. Susan McDougal was supervising the folks who, I think --

Genevieve was one of the folks that were working on it and having a long standing discussions with Tanner.

Q. Was Ms. McDougal involved in the day-to-day negotiations of Tanner then?

A. I would say she was a lot more involved than I am.

Q. What involvement did you have in those negotiations, Mr. Della Fera?

A. I don't think I have ever dealt with the folks. Just in discussions in the office about the acquisition of the product.

Q. Were you advised of the offers that Tanner was making to Fera?

A. I'm sure from time to time, yes.

Q. Isn't it correct that after December of 2016, Tanner made a second offer to Fera in January 11 of 2017?

A. I don't recall.

Q. Isn't it true that in January 11, 2017, Tanner offered to sell Fera seven bottles of 100-count tablets of Daraprim for $177,628 per bottle?

A. Again, I don't recall. If you have something to refresh my memory, that would be helpful.

Q. Did Fera purchase Daraprim from Tanner in January of 2017?

A. No. We never purchased product from Tanner.

Q. Did Tanner come back after January 2017 and made a third offer in September of 2017, Mr. Della Fera?

A. Again, I don't know the dates of the discussions. If you

have something to refresh my memory, I would --

Q. You think Ms. McDougal would know better than you?

A. Yes.

Q. She will be here later today. We can ask her.

You said that Tanner requested prepayment. Isn't it also the case that your company negotiated a 60/40 payment plan with Tanner, 60 percent up front, 40 percent upon delivery of product? Is that something you are familiar with, Mr. Della Fera?

A. I know we negotiated a portion. I don't remember the percentages. But, yes.

Q. So you negotiated those percentages and did that induce your company then to purchase the RLD that it needed for bioequivalence tests?

A. We discussed putting any dollars in escrow, and they had a hard time with that, so we felt very uncomfortable.

Q. That's an answer to a different question I have for you. My question was, did the 60/40 split that you negotiated, or whatever you think the split was, did that induce your company to then purchase RLD from Tanner?

A. I really don't understand your question by saying induced.

Q. To cut to the chase, your company didn't buy RLD from Tanner, no matter what the terms were, correct?

A. They never showed any representation that they had the product.

Q. But you negotiated the 60/40 split, right?
A. As I said, we spoke to them on and off for a long time. They were very difficult to deal with.
Q. And you mentioned an escrow agreement, correct?
A. Correct.
Q. Am I right the purpose of an escrow agreement is to protect the purchaser in case the seller does not come through with the product?
A. Yes.
Q. Mr. Della Fera, isn't it true that your employee Genevieve Della Fera actually sent an escrow agreement to Tanner?
A. I know Genevieve was managing the negotiations.
Q. Did you know that she sent an escrow agreement to Tanner?
A. I don't recall the nuances. If there is anything you want me to look at.
Q. Isn't it true that Tanner signed and returned the escrow agreement to your company?
A. Again, I don't recall that.
Q. That's something that we should take up with Ms. McDougal later today?
A. Yes.
Q. Thank you.

Mr. Della Fera, am I correct that your company decided not to do a deal with Tanner to purchase the RLD it needed for bioequivalence tests because it was not comfortable paying the

sum of money that Tanner was charging for the RLD?
A. We did negotiate price. I do know that. And I was definitely uncomfortable with some of the numbers that they were sharing without proof of product.

And, in essence, on that escrow agreement that I just recalled is that they were putting demands on an escrow agreement where we still didn't have any control, even if they didn't deliver the product. So that was really a big concern. I didn't feel comfortable with this company.

Q. So your testimony is that Tanner was putting conditions on the escrow agreement that you could not agree on?
A. Correct.

MR. POLLACK: Justin, could we pull up Exhibit DX-291, please. Take us to page 4 of 7, please.

Q. Mr. Della Fera, I am going to direct you to the bottom of page 4 of 7 on this exhibit. You'll see that it's an e-mail from Genevieve Della Fera. Is that your daughter and also your employee?
A. Yes.
Q. She is writing to Richard Lambie. His e-mail address is rlambie@tannerpharma.com, copying your colleague, Susan McDougal. I see you're not on this e-mail. You see here, that Ms. Della Fera is writing to Richard Lambie saying: Dear Richard, please see the attached escrow agreement with Fera's wiring instructions and the certification of our purchase order

at end of the document?

MR. PERLMAN: Objection. Foundation, your Honor.

THE COURT: Is this in evidence?

MR. POLLACK: This document is not yet in evidence, your Honor. I'm using it to impeach the witness.

THE COURT: It's not proper impeachment. You could use it to see if it refreshes his recollection.

MR. POLLACK: Your Honor, he said that Tanner was placing conditions on the escrow agreement.

THE COURT: This document does not indicate that their witness was discussing the same document that's being discussed in this e-mail. Perhaps you can lay a foundation.

Q. Mr. Della Fera, have you ever seen this e-mail before?

A. No.

Q. Are you aware of it?

A. As I shared, the relationship with Tanner was over a period of time and there was a lot of back and forth and agreements could have been sent back and forth. But I never agreed on the final document. That's why we never did any business with them.

Q. Ms. Della Fera, she authorized to send out a document that your company has not approved to third parties?

A. It could have happened.

Q. Are you aware of that ever happening with Ms. Della Fera?

A. It could have happened with this negotiation for sure. She

was very emphatic working with these folks, and their salespeople were pretty good.

MR. POLLACK: Justin, you can take that down.

Q. Mr. Della Fera, am I correct that while these negotiations were ongoing with Tanner, Fera was able, in October of 2017, to purchase Daraprim from a local pharmacy called Total Care Pharmacy?

A. Yes.

Q. I believe you purchased two tablets from Total Care using a physician prescription, correct?

A. Yes.

Q. Am I also correct that Fera purchased 70 more tablets from another pharmacy, Walgreens Specialty, also using a prescription written by a physician?

A. Yes.

Q. Both of those prescriptions were filled within just days of requesting them, right?

A. I'm not understanding the question about requesting.

Q. The prescriptions were quickly filled, correct?

A. Yes.

Q. Coming forward now in time to January of 2018, this is something, I believe, you will be familiar with. Your company purchased two 100-count bottles of Daraprim from a procurement company called Reliant, correct?

A. Yes.

MR. POLLACK: Justin, could we pull up Exhibit DX-119, please.

Q. Mr. Della Fera, I've pulled up Exhibit DX-119. It's an e-mail from Satya. Do you know who Satya is, Satya Valiveti?

THE COURT: To the extent you can enlarge a passage for the witness, it would be terrific.

MR. POLLACK: Understood. Thank you, your Honor.

A. Yes. I'm familiar with the gentleman named Satya.

Q. Who is he?

A. He is the representative of Reliant, where we purchased the two bottles of Daraprim.

Q. This e-mail is to Ms. McDougal, a gentleman named Peter. Is that Mr. Florentino?

A. No.

Q. Who is the Peter on this? Do you know?

A. I don't know, but I could guess it's Peter Sketalis, the broker.

Q. You're copied on this e-mail, correct?

A. Yes.

Q. Do you recall getting this e-mail?

A. I am going to look at it. Yes, I recall. It's when we purchased the two bottles.

MR. POLLACK: Your Honor, I move for the admission of DX-119.

MR. PERLMAN: No objection.

THE COURT: Received.

(Defendant's Exhibit 119 received in evidence)

MR. POLLACK: Justin, if we could pull up Exhibit GX-3056, please. I want to go to the bottom e-mail, please. Next page. Are we on the right document here? You see where it says -- go from the top all the way down to underneath Ms. McDougal's signature line. Thank you.

Q. Mr. Della Fera, take a moment to review this e-mail and let me know if you recognize it.

A. Yes. I mean, I would recognize it.

Q. If we look down on the second e-mail in the chain, that's an e-mail from your colleague, Ms. McDougal, acknowledging receipt of the two bottles of Daraprim that she purchased on January 22, correct?

A. Correct.

Q. They got them eight days later?

A. Yes.

MR. POLLACK: Your Honor, I move for the admission of GX-3056.

MR. PERLMAN: No objection, your Honor.

THE COURT: Received.

(Government Exhibit 3056 received in evidence)

Q. Mr. Della Fera, when you purchased the two bottles from Reliant, you had the opportunity to buy up to five bottles, correct? I'm talking about in January of 2018.

A. We were offered more bottles than two bottles, correct.
Q. In fact, you had the opportunity to buy five, correct?
A. You know, I am not sure about the quality. It could have been five or seven. I am not sure yet of the number. It was more than two. So I don't want to parse words.
Q. If you testified to the quantity at your deposition, would that refresh your recollection?
A. Yes.
MR. POLLACK: Justin, could you pull up Mr. Della Fera's deposition testimony, please. We are going to focus on lines 238-24 to 239-5, please.
Q. Mr. Della Fera, please take a moment to read that and let me know if it refreshes your recollection as to the number of bottles you had an opportunity to purchase.
THE COURT: What page of the deposition or pages are we looking at?
MR. POLLACK: Yes. We are looking at pages 238 starting at line 24 and we are running on to page 239, concluding at line 5.
THE COURT: Thank you.
A. Yes, it does help for the recollection. We were going to buy five bottles, correct. We bought two bottles because Satya, the representative of Reliant, mentioned it --
Q. Mr. Della Fera, with respect, I haven't asked another question.

A. I'm just answering your question.
Q. My question was simply, you had the opportunity to buy up to five bottles in January of 2018, correct?
A. That is correct.
MR. POLLACK: Justin, could we go back to Exhibit DX-119, please.
I'm sorry. That's not the one I wanted. Let's go back to 3056 is what I'm looking for. I would like to enlarge the top e-mail, please.
Q. Mr. Della Fera, on February 12 of 2018, it appears that Mr. Valiveti from Reliant wrote back to Ms. McDougal and said: Dear, Susan, please let me know if you need any additional quantity on Daraprim. Correct?
A. Yes.
MR. POLLACK: If we could bring up Exhibit DX-121, please.
Q. Mr. Della Fera, take a moment to review this document and let me know if you recognize this e-mail.
A. Yes, I recognize it.
MR. POLLACK: Your Honor, move to admit Exhibit DX-121.
MR. PERLMAN: No objection.
THE COURT: Received.
(Defendant's Exhibit 121 received in evidence)
MR. POLLACK: Thank you.

Q. Mr. Della Fera, in this e-mail it's Ms. McDougal responding to the last e-mail we just looked at from Mr. Valiveti saying, thank you, Satya. We are good for now. Correct?
A. Correct.
Q. In other words, she is declining Mr. Valiveti's offer to sell your company, Fera, additional bottles of Daraprim, correct?
A. Correct.
Q. At this time I believe we have already established that you know that you need at least five times the amount of Daraprim that you use to manufacture your samples for bioequivalence tests, right?
A. Yes, sir.
Q. That means that you need at least five bottles, correct?
A. It doesn't have to be five bottles. But if the number is 80 tablets, five times eight would be 40 bottles, yes.
Q. In this case it's 100 tablets per bottle, correct?
A. Correct.
Q. So you need 500 tablets, correct, by your math?
A. We need five times the quantity for the bioequivalence study.
Q. That's a yes, you needed five bottles?
A. It's the number of tablets used in the bioequivalence study, and I don't remember. It could be 40 tablets, 60 tablets. It's five times that quantity.

Q. You knew you needed more than two bottles, correct?
A. That is correct.
Q. You had the opportunity to buy more than two bottles in January, correct?
A. Yes.
Q. You had the opportunity to buy more bottles in February, correct?
A. Yes.
Q. Both times you declined that opportunity, correct?
A. Yes.
Q. Without more than two bottles your company would need to seek a waiver from the FDA to forego the five times -- I can't remember -- withholding requirement, correct?
MR. PERLMAN: Objection to form.
THE COURT: Sustained.
MR. POLLACK: Let me rephrase.
Q. Just put it simply this way. Without more than two bottles, your company would have to seek a waiver from the FDA, correct?
A. At that time we were not looking to seek a waiver. Again, if you want me to give you a little color on your question, I can.
Q. Let me see if I can fill in the details here.
Before you even purchased this RLD, you had sent a letter for a pre-ANDA meeting to the FDA in October of 2017,

correct?
A. Yes.
Q. Can you tell us, what is a pre-ANDA meeting?
A. It's to have a formal meeting with the FDA representatives in reference to the application of the pyrimethamine product.
MR. POLLACK: Can we bring up Exhibit 3179, please.
THE COURT: Is this a defendant's exhibit?
MR. POLLACK: This is a plaintiff's exhibit that's, I believe, already in evidence, your Honor.
THE COURT: GX-3179.
MR. POLLACK: G as in go. They sound very similar. I'll try to maybe say gamma X going forward.
Q. Mr. Della Fera, is this the letter requesting that pre-ANDA meeting?
A. Yes.
MR. POLLACK: Can we turn back to page 4. I believe we will see what you were just referencing.
Highlight question 1, please, Justin.
Q. Question 1 that Fera poses: Due to the unavailability of Daraprim tablets -- I'd like to stop there for a moment.
You reference the unavailability of Daraprim tablets in this letter, but you do not refer the FDA to the opportunities Fera had to purchase RLD from Tanner, do you?
A. I think the letter is quite specific to the FDA at the time of Fera's situation, yes. It was unavailable.

Q. You don't refer them to the fact that earlier in time you had the opportunity presented to you to purchase up to seven bottles, correct?

MR. PERLMAN: Objection to form.

THE COURT: Sustained.

Q. Due to the unavailability of Daraprim tablets, Fera requests FDA waive the current draft pyrimethamine product-specific guidance for generic drug development. Fera commits to fully characterize its finished drug product, to include pharmacokinetic study to ascertain PK parameters for the Fera product, enabling the agency to compare our findings to the RLD as follows, and it goes on.

Mr. Della Fera, correct me if I'm wrong, if I understand this correctly, a pharmacokinetic study wouldn't require you to use any RLD, correct?

THE COURT: Would not?

MR. POLLACK: Would not.

Q. Is that what you were describing to me?

A. Just for the record, I didn't write this. It came from our head of regulatory, John D'Angelo.

Q. Did you review it before it went out?

A. Yes.

Q. Back to my question, which is -- I believe it ties into your written direct testimony. What you're requesting here, the pharmacokinetic study would not require you to use any RLD,

correct?
A. Correct.
Q. That's what you were requesting in October of 2017 before you were approached by Reliant?
A. Correct. The unavailability was due to the close distribution model --
Q. Mr. Della Fera, there is no question pending, so I would ask you, respectfully, to wait for a question.
A. Just to correct -- you asked me about the unavailability of Daraprim earlier. I just didn't respond to you because I was thinking of this letter. You did ask that question.
Q. My question to you was, you did not inform the FDA, when you told them that Daraprim was unavailable, that Fera had been approached earlier in 2017 by Tanner Pharmaceutical as late -- strike that. Earlier in 2017 by Tanner Pharmaceutical, correct?
A. We approached many companies who supplied reference product. Tanner is just one that you are bringing up. We never came to an agreement. They never showed proof that they had the product.
MR. POLLACK: Justin, could you just close this document, please.
Q. Am I correct, Mr. Della Fera, that in December of 2017, in fact, it was December 1, the FDA denied this request without a meeting?

A. I don't recall the date, but they did deny it, yes.
Q. Do you remember yesterday we looked at a timeline that you prepared?
A. Yes.
MR. POLLACK: Justin, could we pull up Government Exhibit GX-7015, please. Could you bring it to --
MR. PERLMAN: Your Honor, if I may just object to the statement that Mr. Della Fera prepared this timeline. I don't know that that's in evidence.
THE COURT: It is in evidence. The exhibit is in evidence, right. The objection to the question is sustained.
MR. POLLACK: It's a fair objection. Let me ask another question.
Q. Mr. Della Fera, did you prepare this timeline?
A. No.
Q. Do you know who did?
A. No.
Q. Did someone at your company prepare it?
A. Yes.
Q. Did you review it?
A. I've seen it.
Q. When have you seen it?
A. I don't recall.
Q. Before coming here for your testimony today?
A. Oh, yes.

Q. Did you believe the information on this timeline to be accurate?

A. Yes.

Q. If we can direct your attention to page GX-7015-2. I just want to put a flag pole on the date here. The second entry from the top, December 1, 2017. FDA denies Fera's request for a meeting.

Does that refresh your recollection that that's the date that occurred on?

A. Yes.

Q. At the time Reliant approached Fera with the opportunity to buy up to five bottles of Daraprim RLD in January of 2018, this request to use zero bottles had already been denied by the FDA?

A. Correct.

Q. Then in that case you would agree with me that by January 2018, you would require a waiver if you were to proceed with only two bottles of RLD, correct?

A. I'm not understanding the question.

Q. In January 2018, did you understand, based upon the FDA's denial of your request to do pharmacokinetic testing that if you were to proceed with less than five times RLD that you would need to request a waiver from the FDA?

A. That wasn't even into consideration, no.

Q. But you were aware of the five times requirement, correct?

A. Yes.

MR. POLLACK: I want to bring up Exhibit GX-3177, please, and I want to go to page 3. Again, it's GX-3177. This document is already in evidence.

Q. Mr. Della Fera, this document, dated August 24, 2018, do you recognize this as Fera's first request from a waiver from the FDA for the five-times-RLD requirement?

A. Can you go to the second page. I just want to make sure it's the right document.

(Continued on next page)

BY MR. POLLACK:

Q. Sure.

Are you looking for the language actually requesting the waiver?

A. Correct.

mmo: Justin, why don't we take him to page 6 of the document and highlight numeral 3.

THE WITNESS: That is the document.

BY MR. POLLACK:

Q. So your first request for a waiver was made on August 24th of 2018, correct?

A. That's correct.

Q. That's eight months -- more than eight months after you first purchased the two bottles of Daraprim from Reliant, correct?

A. Correct.

Q. I'm sorry, seven months — let's be fair about it — seven months, correct?

A. That's correct.

Q. Okay. More than six months after Mr. Valiveti offered to sell you additional bottles over the two that you already purchased, correct?

A. Yes.

Q. At the top of what we've got highlighted here, Fera, again, references the difficulty of obtaining adequate supplies of the

RLD, and it says, "Due to that, we request that a waiver be granted for the minimum number of RLD samples required to be retained from the conduct of the Fed and fasting BE studies."

That's what you requested?

A. Yes.

Q. Where Fera references the difficulty of obtaining adequate supplies, it doesn't inform the FDA that it had the opportunity to purchase five bottles from Reliant in January of 2018, does it?

A. Can I explain what you're --

Q. It's a --

A. Would you like --

Q. Does it or does it not?

A. Would you like me to explain it?

Q. I would like you to answer my question, Mr. Della Fera.

A. It doesn't say it.

Q. Another thing it doesn't say, you'll agree with me, it doesn't say that Reliant provided a second opportunity to buy up the five bottles, correct?

A. Oh, that's correct.

Q. It makes no reference of Tanner and the opportunities that Tanner presented to Fera earlier in time to sell Daraprim bottles to Fera, correct?

A. That's correct.

Q. Am I correct that approximately five months later, in

January of 2019, this request for a waiver was -- sorry, yes, January 2019, this request for a waiver was denied?

A. Correct.

MR. POLLACK: Justin, can we bring up GX 3176, please?

Q. Mr. Della Fera, this is --

MR. POLLACK: Your Honor, this is another document preadmitted yesterday.

BY MR. POLLACK:

Q. Mr. Della Fera, is this that letter denying the request for a waiver?

Would it help you to see the language?

MR. POLLACK: Justin, why don't we go to page 3 of 3, please, and enlarge the portion at the end where it says "you should."

Q. Is this the denial of the waiver, this letter?

A. Yes.

Q. And the FDA, in its denial, informs Fera, "You should obtain sufficient quantity of the RLD product, Daraprim (pyrimethamine) tablets USP, 25 mg, to conduct in vivo fasting and fed bioequivalence (BE) studies, and to reserve retention samples for any potential poststudy assessment," correct?

A. Correct.

Q. And after receiving this letter, Fera did not go out and obtain additional RLD, did it?

A. No.

Q. Now, Mr. Della Fera, another three months pass, and in April of 2019, Fera makes a second request for a waiver to the FDA, correct?

A. Yes.

MR. POLLACK: Justin, can we pull up Exhibit GX 3178, please?

I'm sorry, your Honor, I made an error. 3176 was not in evidence. I would like to move for its admission.

MR. PERLMAN: No objection, your Honor.

THE COURT: Received.

MR. POLLACK: Thank you.

(Government's Exhibit 3176 received in evidence)

BY MR. POLLACK:

Q. Mr. Della Fera, GX 3178 is a letter from Fera dated April 5, 2019.

MR. POLLACK: I do believe this is in evidence.

Justin, if we can take Mr. Della Fera to the second page and blow up the paragraph at the bottom.

Q. Does this confirm for you, Mr. Della Fera, that this is the letter representing the second request for a waiver by Fera on April 5, 2019?

A. Yes.

MR. POLLACK: Justin, if we can turn to page 5, please. Actually, let's turn to page 6.

Q. I see this letter is signed by Mr. John D'Angelo, Vice

President of Regulatory Affairs at Fera Pharmaceuticals.

I take it he's one of your employees?

A. Yes.

Q. And before this letter went out, did you review it?

A. Yes.

Q. Did you approve it?

A. Yes.

MR. POLLACK: Justin, let's go back to page 5 for a moment.

Q. Is that the same for all the letters that went to the FDA, did you review and approve them all?

A. Either review or discussed with the head of regulatory.

MR. POLLACK: I'd like to highlight the paragraph following the second bullet point on this page.

Q. Mr. Della Fera, do you see here, it says, "Fera understands that FDA's general policy is not to waive the 'five times testing requirement' at 21 CFR Sections 320.38 and 320.63," and it goes on with some additional citations?

What I want to ask you, sir, is: Does that sentence reflect Fera's understanding?

A. It's written there, yes.

Q. If I understand the timeline of things correctly, just before Fera sent this second request for a waiver to the FDA, in March of 2019 — March 4, to be specific — you and some of your colleagues participated in a phone call with the FDA,

correct?
A. Yes.
Q. What was the purpose of that phone call?
Strike that.
MR. POLLACK: Justin, can we bring up that exhibit, GX 3198. Thank you.
Q. Is this the transcript -- or not a transcript. Is this the written statement that someone at your company read into the phone call?
A. Yes.
Q. And I understand, from your written testimony, the portion that says "Frank Della Fera," you did not actually read because you had laryngitis that day, correct?
A. That is correct.
Q. Someone else read it for you?
A. Yes.
MR. POLLACK: Justin, can we go to the second page, please?
Q. Look down at Mr. D'Angelo's portion.
Did he speak on the call?
A. Yes.
Q. Mr. D'Angelo says: Since we are limited to only 200 tablets of RLD — again, based on what he calls Vyera's anticompetitive activity — on August 29, 2018, we submitted a presubmission meeting package and request where we asked

FDA" --

THE COURT: Slow down.

MR. POLLACK: Yes.

BY MR. POLLACK:

Q. -- to waive requirements for the amount of RLD retained for the bioequivalence study, correct?

A. Yes.

Q. Again, in this statement to the FDA, Fera makes no reference to its opportunity in January and February of 2018 to purchase up to five bottles of RLD from Reliant, correct?

A. Ask the question again?

Q. Sure.

This statement does not reference the fact that Fera had the opportunity in January and February of 2018 to purchase up to five bottles of Daraprim RLD from Reliant, correct?

A. We purchased two bottles.

Q. Well, this letter doesn't even reference that. My question for you, Mr. Della Fera, is: Mr. D'Angelo, when he talks about being limited to only 200 tablets of RLD, he does not state that your company had the opportunity in January, and then again in February, of 2018, to purchase up to five bottles of Daraprim RLD from Reliant, correct?

A. We purchased two bottles from Reliant due to the short dating the product had.

Q. Mr. Della Fera --

A. You want to know why I bought two. I'm going to tell you.
Q. It's a yes or no.
A. Then ask again.
Q. When Mr. D'Angelo says that your company was limited to only 200 tablets of RLD, he omits from that statement that in January 2018, and then again in February 2018, your company had the opportunity to purchase up to five bottles of Daraprim RLD, correct?
A. He does not omit.
Q. He doesn't state it, does he?
A. You can't make me say things that are not true.
Q. Mr. Della Fera, the document will speak for itself.
MR. POLLACK: Let's take it down.
Q. Mr. Della Fera, something else we didn't mention is: In addition to the five times requirement, the bottles have to come from the same lot, correct?
A. Yes.
Q. Am I correct that after you had -- shortly after you had this meeting with the FDA, you were then contacted by the attorneys for the FTC, correct?
A. Yes.
Q. I believe, from your testimony, that was sometime weeks or up to a month after your meeting with the FDA, correct?
A. I don't know the timeline.
Is it on the timeline sheet?

Q. Well, it would be in your deposition. Why don't we bring that up. Let's see if I can find it for you.

MR. POLLACK: Justin, let's go to page 141, line 25, please.

I'm sorry, that's not going to be the right reference. Just give me a moment.

Oh, yes, 141, line 21, through 142, line 16.

Q. Take a moment to read that and tell me if it refreshes your recollection as to when your first call with the FTC attorneys occurred.

A. It states here a couple of weeks or a month, yes.

Q. Since that time, how many conversations have you had with the FTC's attorneys about this matter?

A. I can't recollect how many times. We had a deposition twice, I think, and a conversation prior to the first deposition on the phone.

Q. And at your deposition, you said prior to that, up to a half dozen times, you spoke to the FTC, correct?

A. That sounds correct.

Q. And how many times since then?

A. A handful of times.

Q. Just coming back to your waiver request, getting the timeline right, after you spoke to the FDA, after you met with the FTC's attorneys, that would come forward to June 4, 2019 — this is now two months after your second waiver request — your

waiver was finally approved, correct?
A. Yes.
Q. Following the grant of your waiver on June 4, 2019, Fera was able to conduct its bioequivalence test using the RLD it obtained from Reliant in January of 2018, correct?
A. Yes.
Q. You had made some reference to dating a couple of minutes ago, and I'm not sure what exactly you were referring to, but am I correct that the RLD you had purchased from Reliant had an expiration date of July 2019?
A. Correct.
Q. And using that RLD following the waiver you got in June, you were able to complete your bioequivalence studies, correct?
A. Correct. We didn't need the waiver to complete the bio studies, but for the requirements for the submission of the retains, the waiver helped there, yes.
Q. When did you begin the bioequivalence studies?
A. It happened in May of 2019.
Q. And if Fera had purchased five bottles in January of 2019, it could have started those bioequivalence tests even earlier, correct?
MR. PERLMAN: Objection to form.
THE COURT: Sustained.
THE WITNESS: We weren't prepared --
THE COURT: I'm sorry, there's no question pending.

THE WITNESS: Thank you.

MR. POLLACK: That's correct.

BY MR. POLLACK:

Q. Am I correct that Fera filed its ANDA on December 19, 2019?

A. Yes.

Q. And after you filed your ANDA, the FDA posed certain questions about Fera's API manufacturing process, correct?

A. Could you repeat that, please?

Q. Sure.

After you filed your ANDA in December of 2019, you received inquiries from the FDA regarding the manufacturing process for the API that the API Company No. 1 had manufactured for you, correct?

A. Yes.

Q. If I understand your written testimony correctly, you were unable to timely respond to those inquiries because API Company No. 1 was undergoing staff shortages due to the COVID-19 pandemic, correct?

A. Yes.

Q. And I believe, from your written testimony, you said that those staffing issues at API Company No. 1 were a "decisive factor preventing Fera from timely responding to the FDA," correct?

A. Yes.

Q. In your written testimony, you speculate that had Fera been

able to use Fukuzyu, it would have been able to respond within the review period to the FDA's questions.

That's your testimony, right?

MR. PERLMAN: Objection to form.

THE COURT: Can you direct me to the paragraph to which you're referring, counsel?

MR. POLLACK: Certainly, your Honor.

THE COURT: Is this page 14, paragraph 46?

MR. POLLACK: I believe that's the one, and if the Court would prefer, I can read in his testimony. I'm trying to be -- no, that's not the right one, your Honor. I'm sorry, I didn't write it down. It was an omission by me.

THE COURT: Sustained as to form.

MR. POLLACK: I understand.

Found it. It's paragraph 46, your Honor.

BY MR. POLLACK:

Q. Mr. Della Fera, in your direct testimony, you state, "It is my view that if we had used Fukuzyu as our pyrimethamine API supplier, Fera would have been able to respond within the review period," correct?

A. Yes.

Q. But when Fera reached out to Fukuzyu in late 2015/early 2016, Fukuzyu didn't respond, correct?

A. Yes.

Q. And then, when you reached out again in late 2017/early

2018, you told me that was the purpose of buying a sample, for a comparator test, correct?

A. Yes.

Q. Do you know if Fukuzyu was -- strike that.

And you don't know, and you can't tell us, can you, whether Fukuzyu was having any staffing problems during the COVID-19 pandemic?

A. I wouldn't know.

Q. And using the pyrimethamine that API Company No. 1 manufactured, Fera's ANDA was approved on July 27, 2021; is that correct?

A. Yes.

MR. POLLACK: Mr. Della Fera, thank you.

Your Honor, I pass the witness.

THE COURT: Thank you.

REDIRECT EXAMINATION

BY MR. PERLMAN:

Q. Good morning, Mr. Della Fera. This is Neal Perlman, for the Federal Trade Commission.

Mr. Della Fera, I think I'll just start where defendants left off. Mr. Pollack asked you about your 2017-2018 interaction with Fukuzyu.

Do you recall that discussion?

A. Yes.

Q. And I believe you discussed with Mr. Pollack how Fera was

hoping to use Fukuzyu's sample API for reference testing; is that right?

A. Yes.

Q. Is there any other reason why you were reaching out to Fukuzyu in 2017-2018?

A. I don't recall.

Q. Was Fera hoping to -- strike that.

Were you hoping to enter into a broader business relationship with Fukuzyu if you had been able to obtain pyrimethamine API from them?

MR. POLLACK: Objection; leading.

THE COURT: Sustained.

MR. PERLMAN: I'll do it like this, your Honor:

BY MX. BLACK:

Q. When Fera reached out to Fukuzyu in late 2017 and early 2018, did Fera reach out directly or via a broker?

A. We used a broker.

Q. And who arranged that broker?

A. A consultant of ours, Gary Conte.

Q. What were you planning to do with the pyrimethamine API specifically that you were hoping to procure from Fukuzyu at that point?

A. Initially --

MR. POLLACK: Objection; asked and answered.

THE COURT: Overruled.

You may answer.

THE WITNESS: Initially, we wanted to do a comparator to the API that was being produced by API No. 1.

BY MR. PERLMAN:

Q. What do you mean by "initially"?

A. That was the initial purpose of acquiring a sample.

Q. Were there any other purposes?

A. If we could build a relationship with Fukuzyu, we would have loved to acquire their product.

Q. Why is that?

A. Because they already had an approved DMF, they had been a supplier from day one in the U.S., and we could have started all our activities immediately. We still had a lot of work to do with API 1.

Q. So when you said "their product," did you mean their pyrimethamine API?

A. Yes.

MR. POLLACK: Objection; leading.

THE COURT: Overruled.

BY MR. PERLMAN:

Q. Mr. Della Fera, I'd like to turn now to your discussions with Mr. Pollack about your interactions with Tanner Pharma.

Are you with me?

A. Yes.

Q. Mr. Della Fera, did you have the ultimate authority at Fera

Pharmaceuticals whether to purchase Daraprim RLD from Tanner Pharma?

A. Yes.

Q. And why did you decide not to purchase Daraprim RLD from Tanner Pharma?

A. They never showed proof of product or lot number or expiration date, they demanded prepayment of the material in advance, and we were very uncomfortable -- I was very uncomfortable with that.

Q. What do you mean by "proof of product"?

A. We requested on a regular basis, through the folks who were dealing with them, to show us samples of the product that they were going to sell to us, if they could truly acquire the product. They were asking for the dollars upfront, and we weren't -- I wasn't ready to work with that.

Q. Did the price that Tanner was quoting you change at all through the course of the negotiations?

MR. POLLACK: Objection.

THE COURT: Overruled.

THE WITNESS: It was a roller coaster in pricing, yes.

BY MR. PERLMAN:

Q. What do you mean by "It was a roller coaster in pricing"?

A. They went up, they went down, and I just cut to the chase, show me the product and let us put the money in escrow with our control, and we can do business. They never agreed.

Q. Now, during the time you were interacting with --

THE COURT: So I just have to interrupt.

It is the lot of a federal judge to preside over not just civil cases, but criminal cases. The testimony I have just heard reminds me of so many Title 21 trials over which I have presided where any good negotiation for the purchase of illegal drugs requires a sample upfront. I'm sorry, I just can't restrain myself.

Okay. Please proceed, counsel.

MR. PERLMAN: Yes, your Honor.

BY MR. PERLMAN:

Q. During the time that Fera was negotiating with -- I'm going to strike that.

During the time that Fera was interacting with Tanner, was Fera also in a business relationship with a company called Xcelience?

A. Yes.

Q. Could you briefly describe what Xcelience is?

A. Xcelience is a contract manufacturer and developer for companies like us. We were a virtual drug company, we don't have facilities, and we give them projects to do, and they develop the formulation, and then they manufacture it for us, and they also acquire the RLD, if needed.

Q. Did Xcelience represent to Fera that it would be able to require Daraprim RLD?

A. Yes.

MR. POLLACK: Objection; outside the cross of my scope.

MR. PERLMAN: Your Honor, I'll link up with my next question.

THE COURT: Okay. I'll reserve on the objection.

BY MR. PERLMAN:

Q. Did your experience with Xcelience inform your interaction and your decision not to prepay Tanner Pharma?

A. It was one of the contributing factors.

Q. How so?

A. Xcelience, when they -- we initially signed the contract, they were very confident of acquiring the product, and they said they had very strong sources. As time evolved, I think we signed a contract at the end of one year, and it lasted for about eight months, and they were sourcing on a regular basis for us and could not make an acquisition until they mentioned that they had talked to the RLD manufacturer, Vyera, and they were dealing with them directly. I don't know how and what kind of channels they were using.

Q. How did that inform your interactions with Tanner specifically?

A. About prepaying, I'm not prepaying for product until I can see the product.

Q. All right. So now I'd like to turn to your discussions

with Mr. Pollack about another RLD procurement company, Reliant.

Are you with me?

A. Go ahead.

Q. So how did you come to learn about Reliant?

A. There's a business broker named Peter Sketalis who introduced us to Reliant.

Q. Was that in January of 2018?

A. It sounds right.

Q. Now, I believe you discussed with Mr. Pollack that Fera purchased two bottles of Daraprim RLD from Reliant; is that right?

A. Yes.

Q. Why did Fera purchase two bottles of Daraprim RLD from Reliant and not more?

A. The gentleman representing Reliant was very transparent and shared that his expiration date was the summer of 2019 on the product, that he had the inventory of five or seven bottles of Daraprim.

Q. And why did that expiration date matter for your purchase amount?

A. It's because we weren't sure if we would have our product finally developed because -- finished product. We had to secure a manufacturer and make sure we made three batches, we had to secure the DMF. So timing was still nebulous at that

time.
Q. And why did that nebulous timing affect your purchase decision?
A. It's because the bottles were $115,000 a bottle. If we purchased this -- we purchased two to make sure we can get the activities going, the comparatives, and Satya, the gentleman from Reliant, kept stating that he can get Daraprim anytime for us when we were in January of 2018 in our meeting, so I felt very secure that we can always add on to acquire products when needed.
Q. Now, Mr. Della Fera, you just used the phrase "get our process going."
What did you mean by that?
A. To make sure we complete the DMF with our API manufacturer, to negotiate a contractor to manufacture the product.
Q. When you purchased the two bottles of Daraprim RLD from Reliant, were you intending to use them for BE testing at that point or something else?
A. For development.
Q. What do you mean by "development"?
A. We also do a comparative at the manufacturing site, so we needed samples of the product for it to be manufactured, and we needed samples of the product for doing further testing of the API.
Q. Now, after that January 2018 purchase from Reliant, did you

or any of your colleagues reach back out to Reliant to inquire whether they'd be able to supply additional Daraprim?

A. From the initial meeting, we -- Satya mentioned that he can provide Daraprim at any time for us.

Q. So my question is: Later in that year, did Fera meet with Mr. Valiveti about acquiring additional Daraprim RLD?

A. We had a meeting in May of that year, and he shared with me that he sold his inventory of Daraprim from that summer 2019 lot, and he also signed a contract with Vyera that he would not be able to purchase and resell Daraprim.

Q. Did Mr. Valiveti tell you -- strike that.

At that point, in May 2018, did you view Reliant as a potential source of Daraprim RLD?

A. As of that lunch that we spent time in May, he said he cannot -- he was restricted of dealing with Daraprim. The CEO of Vyera purchased the product, the remaining inventory from him, and then negotiated a deal where it would restrict Satya from continuing sourcing the product for generic companies.

Q. Did the CEO of Vyera -- let me rephrase that.

Was the CEO of Vyera that you were referencing Kevin Mulleady?

A. Yes.

MR. POLLACK: Objection, your Honor; hearsay.

THE WITNESS: It is Kevin Mulleady.

MR. POLLACK: Withdrawn.

THE COURT: Thank you.

BY MR. PERLMAN:

Q. And did you ever have any discussions with Mr. Mulleady about this repurchase of Reliant RLD?

A. Yes. We just happened to have a meeting a week after, and he mentioned what occurred -- hold on. I don't know if it was before or after, but in the month of May. I don't have the dates memorized.

But, yes, I did meet with him, and he actually shared that information, that he purchased the remaining bottles. He actually said he did it personally with his own financing. I don't know. And he mentioned those folks cannot sell Daraprim going forward.

MR. POLLACK: Your Honor, I object. We're now well outside of my cross, and Mr. Della Fera's testimony is hearsay, and I move for it to be stricken.

MR. PERLMAN: Your Honor, if I may --

THE COURT: It's not hearsay, and it's not outside the scope of cross.

BY MR. PERLMAN:

Q. Do you recall anything else about that discussion with Mr. Mulleady about the repurchase of Reliant RLD specifically?

A. I can't recall anything else. If you can refresh my memory on some documents.

Q. Well, let me ask you this, Mr. Della Fera: How did you

feel after you had that interaction with Mr. Mulleady in which he informed you that he had repurchased Reliant's Daraprim RLD?

A. I was taken back and very concerned about the prospect of getting pyrimethamine ever on the market.

Q. Why is that?

A. We'd been discussing this morning about the requirements of having five times the number of tablets for retains for the ANDA submission. Without being able to purchase the product from Satya, we felt -- I felt, personally, that we would not be able to get pyrimethamine completed.

Q. I think with Mr. Pollack, you discussed how Fera acquired some amount of Daraprim via prescription.

Do you recall that?

A. Yes.

Q. Can you use the Daraprim that Fera acquired via prescription for bioequivalence testing or retains?

A. No.

Q. Why not?

A. It's not in the RLD packaging, and without their -- with their referencing of the lot number and expiration date, you can't do it.

Q. Okay.

So I'd like to turn to discussing your interactions with the FDA, which I believe you recall discussing with Mr. Pollack?

A. Yes.
Q. So I think Mr. Pollack asked you a number of questions about why you didn't discuss Reliant's offers in January and February 2018 with the FDA.
Do you recall that back-and-forth?
A. Yes.
Q. Why didn't Fera include those discussions in its letters to the FDA?
A. It's not material. The statement is plugging in something that wasn't the case. We were restricted from purchasing after May from Satya, the Reliant company, and that's when we wrote those letters.
Q. I just want to make sure I understand. So it's my understanding that your first waiver request was in August 2018; is that right?
A. That's correct.
Q. In August 2018, did you view Reliant as a source of Daraprim RLD?
A. Not as of August 2018, no.
Q. Did you view Reliant as a source of Daraprim RLD in January of 2019?
A. No.
Q. And in March of 2019, when you had the telephone conference with the FDA, did you view Reliant as a source of Daraprim RLD?
A. No.

Q. So, Mr. Della Fera, I'd like to, just quickly, turn to asking you a couple of questions about Fera's recordkeeping practices.

I apologize.

MR. POLLACK: Objection, your Honor. I don't believe my cross addressed recordkeeping practices whatsoever.

THE COURT: Let's see if this is tied up.

MR. PERLMAN: Your Honor, this is related to defendant's objection to GX 3286, which we discussed yesterday.

THE COURT: Oh, okay.

MR. PERLMAN: So I'm trying to lay the foundation for that document.

THE COURT: Right.

So, if there's no adequate foundation laid, then this exhibit will be stricken. The defense counsel used the exhibit, I believe, in the cross.

Do you want the exhibit stricken or not?

MR. POLLACK: I did not use the exhibit, your Honor.

THE COURT: You used a different exhibit.

MR. POLLACK: I used a timeline that's actually referenced in Ms. McDougal's affidavit. What Mr. Perlman is referring to are the notes of Mr. Florentino, I believe it was, that are the transcript notes of several meetings between Fera and Vyera.

THE COURT: Thank you very much for that explanation.

So, as I understand it, the defendant still wants this exhibit stricken?

MR. POLLACK: It's many layers of hearsay, your Honor.

THE COURT: Okay. So there will be a foundation or not, and I will hear argument from counsel, and you may have recross on this issue of foundation and anything else you want for recross.

MR. POLLACK: Thank you, your Honor.

BY MR. PERLMAN:

Q. So let me ask you this, Mr. Della Fera:

When Fera has telephone discussions with the FDA, is it Fera's policy to memorialize those discussions?

A. Yes.

Q. Why is that?

A. Because all contact with the FDA — either in teleconference, physical meetings — is placed -- is a contact report in the regulatory department.

Q. Now, when Fera has telephone or other oral discussions with its business partners, does Fera also have a policy to memorialize those discussions?

A. I wouldn't say it is their policy, but it is a common practice.

MR. PERLMAN: Bryce, could I ask you to put GX 3286 up on the screen. I'm actually going to ask you, Bryce, to go to page -- well, I'll ask a couple of questions about this cover

email, so if you could zoom back in, Bryce.

BY MR. PERLMAN:

Q. Mr. Della Fera, did you receive this cover email, GX 3286?

A. Yes.

Q. Are you familiar with this email?

A. Yes.

Q. And who is Scott Florentino?

A. He's the head of business development at Fera.

Q. This email was sent on June 27, 2018, right?

A. Yes.

MR. PERLMAN: Bryce, could I have you go to page 2 of GX 3286. If you could just zoom in on the very top through "Compiled by Scott Florentino." Perfect, thank you.

Q. So did Mr. Florentino create this document?

A. Yes.

Q. Did you direct Mr. Florentino to create GX 3286?

A. Yes.

Q. And why did you direct Mr. Florentino to create GX 3286?

A. I was very uncomfortable with the interaction with Vyera.

Q. Did you --

A. I just wanted to have it documented in detail to understand and to make sure we had it memorialized.

Q. Did you want Fera to have a record of its interactions with Vyera?

A. Yes.

MR. POLLACK: Objection; leading.

THE COURT: Sustained, but I think -- sustained; stricken.

BY MR. PERLMAN:

Q. Do you recall when your discussions with Vyera concluded?

A. The first day of June, early days of June.

Q. When did you direct Mr. Florentino to compile GX 3286?

A. Within that first week.

Q. After Mr. Florentino sent you GX 3286, did you review it?

A. Yes, I did review it.

Q. And did Fera preserve GX 3286 on its servers?

A. Yes.

MR. PERLMAN: The government will move to admit GX 3286 at this time as a business record.

THE COURT: Is this the end of your redirect?

MR. PERLMAN: I had a few more questions, but --

THE COURT: So why don't you finish that.

MR. PERLMAN: Okay.

THE COURT: Then we're going to take our midmorning recess.

MR. PERLMAN: Okay.

THE COURT: I'm not going to rule on this request to admit the document. We'll have our recess. There may be some recross, and any examination that you wish with respect to this document, and then I'll hear counsel if there is a continued

objection.

MR. POLLACK: Your Honor, a point of clarification: Has the document been admitted, or is there recross to the admissibility of the document itself?

THE COURT: It can be -- well, it certainly can be as to the admissibility. I have reserved decision on the objection.

MR. POLLACK: Because if it's admitted, there are questions I would like to get into on the document.

THE COURT: I will allow that, also, if I admit it, but I want to give you a full chance to ask your questions and argue against its admission.

MR. POLLACK: Thank you, your Honor.

MR. PERLMAN: Okay. Thank you, your Honor, I. Just have a few more questions.

BY MR. PERLMAN:

Q. Mr. Della Fera, are you familiar with the phrase "first to market," as it's used in the pharmaceutical industry?

A. Yes.

Q. What does it mean?

A. It means being the first generic player competing against the reference-listed product.

Q. Did you want Fera to be first to market for its generic pyrimethamine product?

A. Yes.

Q. Why?
A. It's usually -- in the generic world is where most of the positive opportunity happens. The pricing is healthy, and you can make tremendous profits.
Q. What do you mean by "positive opportunity"?
A. It's easy to get thorough distribution throughout the pharmaceutical channels when you're first to market.
Q. Mr. Della Fera, in your view, did Fera make efforts to be first to market for its generic pyrimethamine?
A. Yes.

MR. PERLMAN: Thank you, your Honor. I have no more questions.

THE COURT: Great.

So we'll take our midmorning recess and then resume with recross. Thank you.

(Recess)

THE COURT: Counsel?

MR. POLLACK: Yes, your Honor.

THE COURT: Did you have questions for the witness?

MR. POLLACK: Your Honor, not on the exhibit. I don't believe the foundation has been laid on it.

THE COURT: That's fine. Do you have any other questions?

MR. POLLACK: Only about the document, if it is admitted.

THE COURT: Well, you wanted to be heard on that issue.

MR. POLLACK: Precisely, your Honor.

THE COURT: Feel free.

MR. POLLACK: Would you like me to proceed?

THE COURT: Please.

MR. POLLACK: Thank you, your Honor. One moment, I just dropped my glasses on the floor.

THE COURT: No rush.

MR. POLLACK: Your Honor, I don't know what basis on which this document is being offered. Presumably, it seems to be being offered as a business record under Rule 80036. The issue with that is that 80036 requires the document to be made by a person with knowledge at or near the time of the event or occurrence. When we look at this document, on page 1, it is dated June 14, 2018. As we go through the document, we see that it goes to events that go back to '16 and early '18, and in April and May, and finally culminating in June. In fact, I don't even know that it gets to June here.

THE COURT: June 4th.

MR. POLLACK: June 4th. There's the last page, I found it, your Honor. Thank you. And --

THE COURT: So that's all but the first three entries are from January 2018 to June 4th of 2018, and the document is dated June 14th, 2018.

MR. POLLACK: Correct. And the last entry is ten days before this document was even created. And as I pointed out yesterday, the author of this document is not even listed as an attendee at many of the events for which he purports to be providing information. And if we look at other entries, it reflects hearsay within hearsay of what other individuals have told them about what other individuals have said. It's almost three layers of hearsay within this document. And it's impossible to parse out any portion of that to determine what is and is not admissible in this document.

Besides the fact it's not contemporaneous, so I don't see how it's 80036, nor do I see how any of the hearsay statements within this document fits with any exception.

THE COURT: Thank you.

Anything further before I hear from plaintiffs' counsel?

MR. POLLACK: Not from me. Thank you, your Honor.

THE COURT: Thank you.

Counsel?

MR. PERLMAN: Your Honor, I would acknowledge that -- first of all, defense counsel is correct that we are seeking to admit this via 80036 as a business record. It was compiled contemporaneously with the events. As your Honor noted, most of the events were in January, right before this happened, and, as Mr. Della Fera testified, he reviewed -- he directed that it

be compiled and reviewed it to make sure it was accurate for Fera's records.

As to the hearsay within hearsay argument: We concede that the statements made by third parties in this document are hearsay, but I would contend that Fera's statements and Vyera's statements — Vyera employees' statements, such as Kevin Mulleady — as reflected in this document, are not because Vyera's statements would come in as party admissions.

THE COURT: So we can take this line by line with respect to embedded hearsay. And to the extent there isn't a basis to admit the embedded hearsay for the truth, I will not admit it, but to the extent that it is a description of statements by someone associated with Vyera, I do find it is admissible as an exception to hearsay.

If defense counsel wants me to look at any particular line, I'm happy to.

I do find that the creation of the document and the preservation of the document within the files of Fera is sufficiently described as a document created in what is the ordinary course of the business activity of Fera and would ordinarily be kept by Fera.

I admit that the entries are a compilation. I expect that Mr. Florentino talked to people and looked at documents to put together this timeline, but I don't have that evidence, I think, before me, but that's what it appears to be. As defense

counsel points out, how could somebody not involved in these events create a timeline of these events?

So I am going to receive it as a business record, and I am happy to look at any description of a statement made by someone who is not with the company, Fera, and not with Vyera or its agent, I'm happy to look at that more closely, but I expect, generally speaking, that's not the defendant's principal concern here.

Certainly, the fact that the head of Fera directed the creation of this document, as he describes, because of his discomfort with the conversations had with Vyera in the first half of 2018 is, by itself, a reason to admit the document, that fact of creation.

So, counsel, do you want to examine, then, this witness, the document having been received in evidence?

MR. POLLACK: Briefly, your Honor.

THE COURT: Thank you.

(Government's Exhibit 3286 received in evidence)

(Continued on next page)

MR. POLLACK: Your Honor, if you will just indulge me to get situated on this line of questioning, I would appreciate it.

THE COURT: No problem.

MR. POLLACK: Thank you.

RECROSS EXAMINATION

BY MR. POLLACK:

Q. Mr. Della Fera, if I understand your written testimony in paragraph 48, you discuss at least one meeting leading to other meetings between you and two Vyera employees, Mr. Mithani and Mr. Mulleady, in which a joint venture was proposed in which Vyera would provide the rights to Vecamyl, several other projects, and support for a pyrimethamine ANDA to be based on Vyera's ANDA file. Is that correct?

A. Yes.

Q. Now, an ANDA based upon Vyera's NDA file, do I understand that to refer to what's known in the industry as an authorized generic?

A. No. That wasn't the intention. We discussed that to have included that. What they were stating is to use the NDA information of a manufacturing process and to submit it as a new ANDA off the existing NDA data. Actually, to file a new ANDA utilizing all the information that the NDA has. An authorized generic, you don't need to file anything, just for clarity. Authorized generic, if the brand company wants you to

have a label, they can give you have a label and produce product for it.

Q. Was authorized generic one of the things that you discussed with Mr. Mithani and Mr. Mulleady?

A. Yes. This was in discussions.

Q. You and Vyera exchanged several term sheets if I understand the contents of this exhibit, GX-3286, correct?

A. I'm sorry. I don't know what exhibit you're referencing.

Q. Let me put it this way. If I understand correctly, you and Vyera exchanged several term sheets about this joint venture, correct?

A. Yes.

Q. You had several meetings about it, correct?

A. Yes.

MR. POLLACK: Justin, can we bring up GX-3286, please. I would like to take us to page 7.

Q. Mr. Della Fera, I want to direct you to the entry close to the top called May 29, 2018 teleconference. We see the attendees here were yourself, Mr. Florentino, Kevin Mulleady and Akeel Mithani, at least reflected by this document, correct?

A. I'm sorry. What is your question? I was reading.

Q. The attendees. As reflected.

A. The attendees are there, yes.

Q. According to your testimony in paragraph 51, you reviewed

this document and agreed that it was accurate, correct?

MR. POLLACK: Justin, you want to show Mr. Della Fera paragraph 51 of his affidavit, please. You don't need to show them side by side. It's on page 16, by the way.

Q. You reviewed the document and you agree that it's accurate?

A. Yes.

MR. POLLACK: Justin, let's go back to GX-3286, please. Back to page 7, the text that we had highlighted.

Q. One of the things that's highlighted here is that in the course of your discussions about forming a joint venture with Vyera, one of the things Mr. Mulleady proposed that he isn't against is Fera continuing his ANDA development forward, correct?

A. In that teleconference that was discussed.

MR. POLLACK: Justin, can we bring up the entry for May 31 teleconference morning, please.

Q. Mr. Della Fera, here we have a May 31, 2018 teleconference listing attendees being you, Mr. Florentino, Ms. McDougal, and Kevin Mulleady, correct?

A. Yes.

Q. By the way, are these Mr. Florentino's notes that we are reviewing here?

A. These are Mr. Florentino's notes.

Q. Was the same true for May 30, 2018 as well or May 29, 2018?

A. This entire document was created by Mr. Florentino from his

recollection.

Q. But, obviously, not from his recollection for events that he was never present at?

A. Or information or hearsay from that, yes.

Q. If we look at this next meeting --

A. And the correction is there are no attorneys on the attendees. There was attorneys from both sides.

Q. There were attorneys on the line too?

A. Yes.

Q. Who was your attorney on the line?

A. Shon Glusky.

Q. What firm is Mr. Glusky at?

A. Shepard Mullin.

Q. What is his specialty? Do you know?

A. No.

Q. And Vyera had a lawyer on as well?

A. Many.

Q. Is this the first time lawyers were on the calls between you and Vyera?

A. All these teleconferences were attorneys with the red line.

Q. When you say red line --

A. With the discussion -- you just mentioned the term sheet.

Q. The term sheet?

A. Yeah.

Q. Thank you.

Again, when we look at this meeting from May 31, 2018, if we go down four, Fera can continue to move its ANDA development forward. Again proposed, correct?

A. That's what's written.

MR. POLLACK: Justin, you can pull that down.

Q. Mr. Della Fera, isn't it a fact that -- excuse me. I want to phrase this correctly, sir. Isn't it a fact, Mr. Della Fera, that you did not have a genuine intention of entering into a joint venture agreement with Vyera?

A. I really can't answer that.

Q. You can't answer that?

A. No.

Q. Perhaps your deposition will refresh your recollection.

MR. POLLACK: Justin, can we bring up his deposition. Let's go to the deposition at page 262, line 12 through page 263, line 6.

Q. Mr. Della Fera, take a moment to read that. Tell me if it refreshes your recollection of whether you had a genuine intention of ever entering -- genuine intention of entering into a joint venture agreement with Vyera.

A. Again, very mixed emotions, yes. When we were dealing with Vyera, Mr. Mulleady, you forgot that we just discussed --

Q. Mr. Della Fera?

A. Hold on.

Q. I asked a question that required a yes or no.

A. If you just want yes or no. I said mixed emotions. I did not come to a finalization. What I did finalize is, I was not doing business with Vyera, absolutely.

Q. Mr. Della Fera, the attorneys at your deposition asked you, Mr. Cravens from the Morgan Lewis law firm: Did you ever have a genuine intention of entering a joint venture agreement with Vyera? Your answer was: I think my statement would answer that. Your statement above was: I needed to know as much as I could learn to make sure I complete my project.

MR. POLLACK: You got to go higher, Justin. Sorry.

Q. You said: I personally took all the actions as CEO and one of his directors in our negotiations could find out where we were in our development. I was very guarded. But it's the old adage, keep your friends close, but keep your enemies closer. And he volunteered to come and wanted to be closer. I needed to know as much as I could learn to make sure I could complete my project without interference.

Mr. Cravens asked you: So were all of your efforts to negotiate a joint venture agreement with Vyera in fact just an effort to keep your enemies closer? Your answer was: I was trying. OK, yes. That is one of the -- I was just using at a metaphor, but just to find out as much as I could find out and ensure that would be successful.

Was that the statement that you were referring to in your answer as to whether you ever had a genuine intention of

doing a deal with Vyera?

A. Again, as I stated, I think that's clear. What you just read you can use as my statement.

MR. POLLACK: No further questions, your Honor.

THE COURT: Any additional questions?

MR. PERLMAN: Your Honor, I just have one question for the witness.

REDIRECT EXAMINATION

BY MR. PERLMAN:

Q. Mr. Della Fera, what do you mean by mixed emotions in your dealing with Mr. Mulleady and Vyera?

A. When he initially contacted me, I was open to listening and understanding what they wanted to do. As soon as the actions were taken when he purchased the remaining Daraprim from Satya at Reliant, I knew I had trouble. I had a problem. And I had to understand the problem, how to manage it.

Q. Did Mr. Mulleady describe any other actions that led you to believe you had a problem?

A. The other action was when he shared with me in a lunch meeting in the month of May or April, I am not sure of the date exactly, what he did to two competitors of ours. One is Mylan and the other is Sandos. Those are two big drug companies in the generic market at that time. He took out their API manufacturer called RL out of India, RL Fine, I think it is called, by going there, flying out there, meeting with the top

executives. I don't know who they are. And he negotiated a deal to have an exclusive supply arrangement with Vyera, and he said he was paying them on a regular basis a royalty of sales of Vyera.

Q. How did that discussion make you feel, Mr. Della Fera?

A. Very uncomfortable.

Q. Why?

A. It was unsettling to hear such behavior.

Q. Why was it unsettling?

MR. POLLACK: Your Honor, can I ask Mr. Perlman to move a little closer to the microphone.

MR. PERLMAN: Sorry.

Q. Why was it unsettling?

A. It's bad behavior. I don't want to go any further. I didn't want to deal with a person like that, like a character.

MR. POLLACK: Objection. Leading.

THE COURT: Overruled.

Q. Did Mr. Mulleady mention anything else at the meeting concerning API's supply?

A. He shared in this document that a consultant firm produced for him just weeks before we met, sharing that he knew who my API supplier was.

Q. How did that make you feel?

A. Unsettled.

Q. Could you elaborate, please.

A. That what he did to Sandos and Mylan with RL Fine by doing an agreement to prevent the product from being produced, that he can do the same to my API supplier.

MR. POLLACK: Objection, your Honor. I object to the foundation of this witness' testimony about what Mr. Mulleady did or did not do as to two other API suppliers, which there is no evidence in the record on.

THE COURT: I'm sorry. I thought he was relating a conversation with Mr. Mulleady. I think your objection is overruled.

MR. POLLACK: If it's for the truth, it would be objectionable.

THE COURT: Overruled.

MR. POLLACK: Thank you, your Honor.

MR. PERLMAN: Your Honor, no further questions.

THE COURT: Any further recross?

MR. POLLACK: No, your Honor. Thank you.

THE COURT: Mr. Fera, help me put together a timeline. In a world which may be a more normal world, which is not the world you met.

When did you contact Fukuzyu for the second time seeing if you could get some API from them? Do you remember?

THE WITNESS: From the documents it was in 2017.

THE COURT: Sort of towards the end?

THE WITNESS: Yes.

THE COURT: Is there anything I can look at to put a date on that?

THE WITNESS: There was -- there should be many e-mails from Susan McDougal's files with our consultant, Gary Conte, who was connecting us because we failed on our own. They wouldn't even talk to us.

THE COURT: Hypothetically, just for our discussion, I am just going to look for those e-mails in the record, but if they aren't in the record, so be it.

To start us off, I am going to pick a month, November of 2017. Let us say Fukuzyu answers your inquiries this time and that those discussions go well. They are willing to supply you with API.

THE WITNESS: Yes.

THE COURT: In the best of all possible worlds, wherein you had no interference in the market, what would you have done at that point?

THE WITNESS: We would have negotiated a supply agreement with Fukuzyu immediately.

THE COURT: Did you need a supply agreement? Why couldn't you just purchase the API?

THE WITNESS: We would have purchased API to test it. But the second thing, if we had the channels opened in our relationship, we would have locked into an agreement.

THE COURT: Why did you want a supply agreement?

THE WITNESS: It's because the product has been commercially available in the U.S. It has an approved DMF. It wouldn't have the little wrinkles that we have with our API number 1 with the impurity profile because when you're on the market you have to keep up to the standard. And if there is any questions from the agency, it gets addressed while you're in the market.

THE COURT: So as opposed to just sending over a purchase order to buy the API as you needed it, you would have wanted a supply agreement with Fukuzyu as well?

THE WITNESS: Yes.

THE COURT: What advantage do you get from a supply agreement?

THE WITNESS: That we would have a consistent supply going forward, not just one purchase.

THE COURT: So you would want to negotiate terms that gave you confidence in the supply going forward?

THE WITNESS: Yes.

THE COURT: How long do you think it would have taken you in the normal course, based on your business experience? With a willing manufacturer, willing to enter into an agreement, a supply agreement with you, how long to negotiate and sign that?

THE WITNESS: Within three months. We would have probably worked faster if we had a cooperative partner, as

Fukuzyu, as you're stating on the hypothetical. We would have immediately requested materials and start working just on the premise of in good faith that we would enter into an agreement.

THE COURT: On my hypothetical you would have gotten an immediate supply of the API which you could use?

THE WITNESS: Yes.

THE COURT: And you would have used about perhaps two, three months or so to negotiate a supply agreement?

THE WITNESS: Correct.

THE COURT: Then what other partners do you need in order to create the pyrimethamine?

THE WITNESS: A manufacturing partner that makes the finished product.

THE COURT: Would that be a manufacturing partner in the United States?

THE WITNESS: It doesn't have to be. Our partner for pyrimethamine is in Switzerland.

THE COURT: As of November 2017, did you have a relationship with that partner?

THE WITNESS: I had a relationship with that partner, yes, but we did not come to terms yet.

THE COURT: Now that you know, in our hypothetical, in November of 2017 that you have API in hand and you have a willing partner to negotiate a supply agreement, how long to finalize that agreement with your manufacturing partner?

THE WITNESS: Within 90 days. And we would have many choices. This is the -- the formulation is a simple formulation that could be produced almost anywhere that is producing tablets.

THE COURT: Under my hypothetical you also can go out and just get as much Daraprim as you want.

THE WITNESS: OK.

THE COURT: Forgetting Daraprim, normally when you are developing a generic product do you have trouble getting access to the RLD?

THE WITNESS: No.

THE COURT: So under my hypothetical you have no problem getting access to the RLD?

THE WITNESS: OK. That would be very helpful.

THE COURT: What's the next step?

THE WITNESS: You acquire -- it takes within a week, two weeks to get the RLD from our supplier, our regular supplier that we used.

THE COURT: So now you have the RLD in hand. You know it took you until about February of 2018 to have a contract executed with your Swiss manufacturing partner. What's the next step?

THE WITNESS: For the partner to make the exhibit batches, which is three batches.

THE COURT: How long do you expect that would take?

THE WITNESS: That takes three to four months. On your hypothetical, we would have done this much early earlier.

THE COURT: Because?

THE WITNESS: I had no barriers. When we decided to make the product.

If I could just enjoy this hypothetical a little bit, if we make the decision in the fall of 2015, I could have started the project -- with the way the environment that you are sharing with me, we could have started in early '16 and we could have probably been filing our ANDA to the FDA by the third quarter of '17, maybe the fourth quarter of '17, and get the approval probably in 12 months, third quarter or fourth quarter of '18.

THE COURT: Stick with my hypothetical, though.

THE WITNESS: I'm having a good time.

THE COURT: The three batches are taking three to four months to manufacture after you have your agreement with your manufacturing partner in Switzerland.

THE WITNESS: Yes.

THE COURT: We are going to say June of 2018.

THE WITNESS: OK.

THE COURT: What happens next?

THE WITNESS: You -- one of the components after production, you have to wait six months of stability data of the finished product that you produced at your contract

manufacturer. So let's say everything was produced probably in April, May. Add six months. So we are looking at November. Then we receive that six months data, which on the hypothetical everything worked out. The product is good. Then we assemble our ANDA file.

THE COURT: You only assemble the file after the six-month period, or are you working on that in the meantime?

THE WITNESS: We are working on it. You start working on it much earlier. You just keep adding the data set points as it comes about. The regulatory department would be working on the ANDA. It would be working on it even before those batches were made.

THE COURT: So once you have the six-month data in hand, how long to file the ANDA?

THE WITNESS: We try to turn it around in 30 days.

THE COURT: So our dates in this hypothetical may be a little off, but that means the ANDA is filed in January of 2019 in my hypothetical.

THE WITNESS: It's a little late, but, yeah, I think it would have been a little earlier.

THE COURT: And then you had a problem when you filed your ANDA this time with some questions that came back. Would you have expected, under our hypothetical, the same kind of questions to come back from the FDA?

THE WITNESS: No.

THE COURT: Why not?

THE WITNESS: Because the API, if we were using Fukuzyu, wouldn't have those problems -- those questions. Our product didn't have problems, but had those questions, probably had already been answered, historical.

THE COURT: So the questions related to the API formulation that company A or the process for creating the API that company A used?

THE WITNESS: It was the impurity profile of the product. And there was -- those undetectable impurities that usually you group up together and say as long as it's less than a certain level, it doesn't matter. This time the agency asked, because it's a new API supplier, can you identify those. Then it took us 10 months or eight months to do that. That was a long one, and very expensive.

THE COURT: So you don't, under this hypothetical, have those questions asked. You filed an ANDA in January of 2019. How long would you have expected to wait for ANDA approval with no questions?

THE WITNESS: Eight months. Because we had a target -- when we file it in December of '19 on our own ANDA, not the hypothetical, because we were under the CGT status, it's something that the agency developed kind of right after Daraprim was launched to help generic companies come up and genericize all types of pharmaceutical drugs, even if they are

very low in sales. So we would have alternatives in the marketplace.

They came up with this new program which they would kind of expedite the approval process and give you a target date when you submit your ANDA. When we submitted our ANDA in December '19, we received from the agency a target date for approval by August of '20. You would add eight months to your January hypothetical. It would be September of '19, the approval.

THE COURT: How long to be in the market after your approval date?

THE WITNESS: How long it would take?

THE COURT: Yes.

THE WITNESS: We would already have the product being produced at our contract manufacturer. So within the 30 days after the approval we would be on the market.

THE COURT: The CGT status, when did the FDA institute that, roughly? Is that a longstanding program?

THE WITNESS: No. It's relatively new. Commissioner Scott Gottlieb. That took place, I think, in 2016 I'm guessing on the year, but I think it's '16 or '17, but it was '16.

THE COURT: Thanks.

Give me one moment, counsel.

(Pause)

THE COURT: Let me just check and see if I have other

questions. Sorry.

At paragraph 46 of your direct testimony, which is on page 14, at the last sentence you refer to a letter that you responded to. And to just focus your attention on this passage, you're talking about a response to the FDA letter and that you responded to the FDA letter in 2020.

Counsel, is the last sentence in that paragraph redacted from public testimony?

MR. PERLMAN: No, it is not, your Honor.

THE COURT: In that last sentence you say: In the interim, we divested this product, which is approved on July 27, 2021.

What do you mean, divested?

THE WITNESS: We licensed the product or sold the product to another company.

THE COURT: Thank you.

Counsel, do you have any questions for this witness based on what I asked?

MR. PERLMAN: One very short question.

REDIRECT EXAMINATION

BY MR. PERLMAN:

Q. Mr. Della Fera, what does CGT stand for?

A. Competitive generic therapy.

MR. POLLACK: Your Honor, very briefly.

THE COURT: Yes.

MR. POLLACK: Justin, will you pull up Exhibit GX-7015, please.

RECROSS EXAMINATION

BY MR. POLLACK:

Q. Mr. Della Fera, this is the timeline that's been introduced into evidence in the case.

MR. POLLACK: I plan to get into some of this with Ms. McDougal, your Honor, but I thought I would preview some of it now, in light of your questions. You may find it of assistance.

Q. Mr. Della Fera, when we look at page 1., you have already testified to this, October 25, 2017, Fera completed its manufacture of API, correct?

A. Yes.

Q. Prior to API company number 1 manufacturing that batch of API, your company had been working with a CRO, a credit research organization, called Xcelience, is that right?

A. Yes.

Q. And you terminated Xcelience in July of 2017 because of its inability to source RLD, correct?

A. Yes.

Q. When we look at the timeline on page 2 at the top, we see that from July until November you didn't have a CRO, correct, for this product, the generic Daraprim?

A. I'm sorry. Can you reask the question.

Q. Let me ask it a different way. That was inartful.

Now, on November 1, 2017, after terminating Xcelience in July, Fera contracts with another CRO, Latitude, for development of a generic pyrimethamine prototype, correct?

A. Yes.

Q. Now, Xcelience was a company that was able to do both the prototype and then the manufacturing you would need to do your bioequivalence tests, correct?

A. Yes.

Q. Latitude could only do the prototyping, correct?

A. Yes.

Q. So you contract with Latitude in November of 2017. We look down the page. October 25, 2018 is when Latitude completes the prototype and transfers its manufacturing process to Fera's contract manufacturer, Rivopharm, correct?

A. Yes.

Q. And Rivopharm completes its first manufacturing campaign of Fera's generic Pyrimethamine in March 2019, correct?

A. Yes.

Q. Thank you, Mr. Della Fera. No further questions.

THE COURT: Counsel, I just want to make sure I understand the significance of the questions you have just placed.

Are you trying to say from this document that some of the timeline that Mr. Della Fera has just given me is less than

reliable?

MR. POLLACK: It's not grounded in reality because --

THE COURT: I'm sorry. I didn't capture that. What particular part of the timeline do you think is inconsistent with what you pointed out on this chart?

MR. POLLACK: Sure. Your Honor, I did not catch all of Mr. Della Fera's assumptions. But the biggest one is that, number 1, they had API --

THE COURT: Just put the questions to the witness so it's clearer to me what point you want me to draw from this, if you could.

Q. Mr. Della Fera --

THE COURT: You told Judge Cote the following, that it took X amount of months to accomplish this task, whatever you want me to focus on.

MR. POLLACK: Your Honor, my point is simply this.

Q. Mr. Della Fera, you could not begin bioequivalence tests until Rivopharm manufactured the Daraprim -- the generic Daraprim product based upon Latitude's prototype manufacturing process, correct?

A. That is correct.

Q. So the earliest that you could begin bioequivalence in the real world, and you had another RLD to conduct it, would have been March of 2019, correct, when Rivopharm completes its first manufacturing campaign of Fera generic pyrimethamine?

A. That's correct.

MR. POLLACK: Thank you, your Honor.

THE COURT: Thank you.

Any questions?

MR. PERLMAN: No, your Honor.

THE COURT: Mr. Della Fera, I did not understand that last line of questions.

Explain to me, where in the timeline that you gave me, the hypothetical world which you hope would be the world in which you usually operate your company, where does bioequivalence testing fit within that? Is that the three to four months in which the three batches are produced and tested?

THE WITNESS: Correct.

THE COURT: Where is the bioequivalency testing take place.

THE WITNESS: The bioequivalency takes place right after you produce those three batches.

THE COURT: How long does it take?

THE WITNESS: It's either two to six weeks in total. You have to schedule it. It's not long.

THE COURT: And you told us that the product has to sit on a shelf for six months to do the stability testing. Where does the bioequivalency testing fit within the framework of the six months that you have to wait?

THE WITNESS: Just to use pyrimethamine as the

example, we had the product produced in March of '19. We did the bioequivalency test in May of '19. Parallel the six-month testing is happening at that same time.

THE COURT: So you do the bioequivalency testing during the period where you're testing the shelf-life stability of the product?

THE WITNESS: Correct.

THE COURT: Questions that counsel just put to you were addressed -- perhaps you understood -- what part of this chronology in the production and approval process were they addressed to?

THE WITNESS: I think he was using -- we have that date, October 25, I forgot, from 2018 is when the API was produced. And he goes, you didn't start doing or finish your tableting until March of '19. That makes sense. We had to get the API. We had to ship it from India to U.S. to our Swiss friends. Probably got there by the new year. And they started working on the preproduction batches probably late January, February, completed probably early March. That's what he was referencing on the dates.

THE COURT: Bringing your attention to those real-world activities that you experienced in your development of the generic pyrimethamine, does that change any of the hypothetical that you and I discussed just a few minutes ago?

THE WITNESS: I think it was very clear that three

months, four months -- no. I don't think it changed anything. But he was identifying what we did.

THE COURT: Thank you.

Counsel, any questions based on the questions I put to this witness?

MR. PERLMAN: No, your Honor.

MR. POLLACK: No, your Honor. Thank you.

THE COURT: Thank you.

You may step down.

(Witness excused)

THE COURT: Next witness.

MR. MEIER: Your Honor, the government calls as the next witness Susan McDougal. My colleague, Neal Perlman, will also handle this witness.

THE COURT: Ms. McDougal, if you could come up here and take the witness stand.

If you could remain standing and face me, please. Take the witness stand. Remain standing. Race your right hand.

SUSAN McDOUGAL,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

THE COURT: Ms. McDougal, I think you are about to be handed a document which bears a government exhibit number.

THE WITNESS: Excuse me, your Honor. I left my

glasses in my bag. Can I get them?

THE COURT: Certainly.

THE WITNESS: I apologize.

THE COURT: Someone is bringing your bag right over to you.

THE WITNESS: Thank you.

MR. PERLMAN: Your Honor, it's GX-8008.

Your Honor, I would just note that Mr. Della Fera is still in the courtroom. I just want to make sure that that's all right with you.

THE COURT: I think his testimony is completed.

Is there any objection to Mr. Della Fera remaining in the courtroom?

MR. POLLACK: No. I do not intend to recall Mr. Della Fera. Thank you, your Honor.

THE COURT: Thank you, counsel.

Ms. McDougal, take your time. Get your glasses.

THE WITNESS: I have them.

THE COURT: Ms. McDougal, you've been handed Government Exhibit 8008, if you could turn to the 13th page.

THE WITNESS: Yes.

THE COURT: Is that your signature at the bottom?

THE WITNESS: Yes.

THE COURT: Did you read this document with care before signing it?

THE WITNESS: I did.

THE COURT: And you swear to the truth of its contents?

THE WITNESS: I do.

THE COURT: Is there any objection to the receipt of GX-8008?

MR. POLLACK: Yes, your Honor.

We have some objections to the content of the affidavit. I am going to move the microphone closer so you can hear me better.

THE COURT: Sure. Or you can walk over to the podium, if you would like.

MR. POLLACK: I'm perfectly appropriate at the podium. Thank you, your Honor.

THE COURT: Thank you.

MR. POLLACK: Your Honor, unfortunately, when I take off the mask, it pulls my hearing aids out with it.

THE COURT: Take your time, counsel.

MR. POLLACK: Thank you.

Your Honor, I was about to begin. As colloquy, many of these are going to be similar to objections that we raised with Mr. Della Fera. So I expect your rulings will be similar, but I raise them to preserve the record.

To begin, your Honor, paragraph 12, when we look down and we see Ms. McDougal testifying about -- there is a sentence

here that starts: Even better.

THE COURT: Paragraph 12 has a sentence in the middle that begins: Even better.

MR. POLLACK: Paragraph 12. Even better is when a DMF holder's API is used --

THE COURT: Slow down.

MR. POLLACK: -- used in an FDA-approved product because that provides additional assurances that the API supplier is reliable and likely to pass FDA muster.

Your Honor, based upon this witness' experience in marketing of pharmaceuticals, I don't believe a foundation has been laid for this testimony, which is speculative and improper lay testimony.

THE COURT: Objection overruled. It comes out of her work experience as described in her affidavit and is appropriate lay opinion testimony under 701.

MR. POLLACK: Your Honor, in paragraph 13 we raised the same objection to the provision that begins -- second line up from the bottom with the word which, but we should read the entire sentence to understand it in context. Developing it in API from scratch takes a long time and involves a lot of trial and error. The portion we object to is improper speculation and improper lay testimony which can lengthen the approval time significantly, and the FDA often has questions about a new manufacturing process.

THE COURT: Overruled.

MR. POLLACK: Your Honor, in paragraph 37 there is a sentence -- this paragraph discusses -- strike that one. Your Honor.

Paragraph 41, similar to Mr. Della Fera, Ms. McDougal posits about five lines up, starting with the word if. Your Honor appears to be at the same spot as me now. If we had used Fukuzyu as our API supplier, I find it very unlikely that the FDA would raise this issue, given that it was already familiar with Fukuzyu's manufacturing process. Again, your Honor, we find that to be speculative and improper lay opinion.

THE COURT: Overruled.

MR. POLLACK: Finally, your Honor, my last objection, I promise. We object to the last sentence in paragraph 42, which talks about what could have happened had Fera been able to respond to FDA's inquiries and avoid the complete response letter. Again, we find this to be speculative and improper lay testimony.

THE COURT: Overruled.

Now I am not taking this testimony as evidence of what the FDA would or wouldn't have done but to shed light on the expectations within the industry and its understanding of the process.

Anything else, counsel?

MR. POLLACK: No, not from me. Thank you, your Honor.

THE COURT: Thank you.

MR. POLLACK: Your Honor, I meant to raise this in colloquy before we got started, but there is an issue, and I know your Honor's preference is that if we are to seal the courtroom to do it at the beginning or end of testimony. I do want to get into a document that Fera has asked to seal. I suggest I'm ready to do it now. It's DX-280.

THE COURT: GX-8008 is received.

(Government Exhibit 8008 received in evidence)

THE COURT: How long do you expect your examination to take?

MR. POLLACK: Not very long, your Honor. You mean my entire examination or the sealed portion?

THE COURT: On this document.

MR. POLLACK: Five, ten minutes. Maybe not even.

THE COURT: I'll ask anyone who is not counsel for the plaintiffs, counsel for the defendant, or with Fera to leave the courtroom.

We can't cut the feed to the overflow courtroom. My deputy is going to the overflow courtroom to make sure no one is in it.

MR. MEIER: Your Honor, I do not recognize who the woman is in the back.

That's counsel for Vyera. I am not sure if they are permitted --

THE COURT: They are not.

Do you have a copy of the document for me, counsel, as we wait?

Can you display it on the screen for me?

MR. POLLACK: I can. I only have my own copy, your Honor, and it's highlighted for my convenience. I would like to keep it. We are not going to use the redacted.

THE COURT: The overflow courtroom is empty. You can proceed, counsel.

MR. POLLACK: Thank you, your Honor.

(Pages 538-545 SEALED)

AFTERNOON SESSION

2:01 PM

(In open court)

THE COURT: Ms. McDougal, you may retake the witness stand.

Counsel.

MR. POLLACK: Thank you, your Honor.

SUSAN McDOUGAL,

CROSS-EXAMINATION CONTINUED

BY MR. POLLACK:

Q. Ms. McDougal, I'd like to talk to you about Fera's activities surrounding -- by the way, you can take off your mask. I'm going to remove mine.

A. All right. Thanks.

Q. That's better, right?

A. Yes.

Q. As I was starting to say, I'm going to turn your attention to Fera's efforts and activities surrounding the acquisition of Daraprim reference listed drug, or RLD, okay?

A. Okay.

Q. When did those efforts begin?

A. I believe -- pretty much, I think, the first time we reached out -- I have to reference because I don't have the dates memorized, if that's okay? I know it's in the testimony.

I don't remember the exact date, I'm sorry, but it was

early in the process once we identified the opportunity.
Q. And Fera, among other things, attempted to do this through its contracting research organization, Xcelience, correct?
A. I think that was a little bit later.
Q. Okay.
A. Because I know we started to work with Xcelience in the December '16 time frame, and that was one of the reasons why we worked with them, because they said they could procure RLD.
Q. Now, if I'm correct, I believe your efforts, and Mr. Della Fera said it, started in as early as 2015; is that right? I'm sorry, 2016?
A. Yeah, yes.
Q. When did you contract with Xcelience?
A. In December of '16, I believe.
Q. When we say CRO, contract research organization, that is an entity that your company hires to do the manufacturing work, correct?
A. Yeah. Actually, technically, the CMO is a contract manufacturing organization, and, generally, they can do development, manufacturing. Some only do manufacturing. CRO is more research.
Q. Your firm is what you would call a virtual pharmaceutical company, correct?
A. Yes.
Q. You don't actually have your own manufacturing facilities,

you outsource that to other companies like Xcelience, Latitude, Rivopharm?

A. Yes.

Q. In addition to being a CMO, was Xcelience also working on your behalf in an effort to obtain Daraprim RLD?

A. Yes.

MR. POLLACK: If we bring up GX 3469, please.

I was asking counsel if he had the list of exhibits we handed up earlier, but it's okay, I'll proceed.

Q. Ms. McDougal, we've put up on the screen an email from Ben Sahacic to you dated June 27, 2017. Take a moment to look at this email. Its subject is "Re Xcelience New Order PO No. 4500061546 - Daraprim."

Let me know if you've seen this email before and recognize it.

A. You want to know if I've seen this before? It was to me, so I'm sure I read it, but do you want me to read it now?

Q. Well, who's Ben Sahacic?

Am I saying it right?

A. I think it's Sahacic. I don't know.

So he's with Capsugel, which had acquired Xcelience at some point in the time frame that we were working with them.

Q. Did you and Mr. Sahacic correspond during this time period about efforts to procure RLD?

A. Yes.

Q. And if we look at the top of this email, he appears to be writing you: "Hi Susan. Let us know how you would like to proceed with RLD, please. The attached came through from Turing via our vendor. You'll notice they changed the quantity to 13 bottles."

Do you see that?

A. I do.

Q. Is this email describing an opportunity on June 27, 2017, for your company, Fera, to purchase RLD from Vyera, then known as Turing?

A. Yes.

Q. And if I read Mr. Sahacic's email correctly, Vyera — which is how we're referring to Turing today, just so you know — Vyera actually sent a purchase order back to Fera for review, correct?

MR. PERLMAN: Object to form.

THE COURT: Sustained.

THE WITNESS: It wasn't --

THE COURT: There's no question pending.

BY MR. POLLACK:

Q. That's correct.

Ms. McDougal, is it correct that Vyera sent a purchase order back to Fera for review?

A. That's not my understanding, no.

Q. Did you get a purchase order through Mr. Sahacic?

A. No.
Q. I'm sorry, a purchase agreement. Did you get a purchase agreement from Vyera?
A. Yes.
Q. So I misspoke, and I apologize for that. It's my mistake.
And that purchase agreement, if we turn back three pages, that's what's attached to this email?
A. It appears, yes.
Q. And, of course, this is in draft form, correct?
A. I believe it was the first time it was being presented to us, yes.
Q. How many times was this purchase agreement traded back and forth with Vyera?
A. Between Fera and Vyera?
Q. Yes.
A. I know we reviewed it once, if I recall correctly, and we sent back -- not directly, we were using -- Xcelience was the in-between, and they had their third-party procurement, so I believe we sent it back once to Xcelience.
Q. So I understand what you're saying, you did not have direct communications with Vyera?
A. That's correct.
Q. You communicated through them via an intermediary, in this instance, Xcelience?
A. Yes.

Q. And down in the first whereas clause, we see what Mr. Sahacic was referring to in his email. It says, "Whereas company wishes to purchase 13 bottles of Daraprim, 25 mg, NDC," and it provides a number here, "through AdiraMedica, a third party, for use in certain bioequivalence studies," correct?
A. Correct.
Q. Is that what Fera was inquiring into, for the purpose of purchasing Daraprim RLD to do bioequivalence studies?
A. That was -- yes, correct.
Q. And who drafted this purchase agreement; do you know?
A. I was told it was drafted by Turing and then Turing's attorney.
Q. So someone from Turing drafted this purchase agreement and sent it to you via Xcelience?
A. Correct.
Q. This wasn't an agreement that Fera drafted and sent to Turing for review?
A. No.
Q. Do you recall receiving this email and this attachment?
A. Yes.

MR. POLLACK: Your Honor, I would move to admit this document, GX 3469, if it hasn't already been admitted. I believe it may have this morning.

THE COURT: Received.

(Government's Exhibit 3469 received in evidence)

MR. POLLACK: Thank you.

Bring that back up, please. Let's go to the next page, please, Justin, page 4. Let's highlight everything from G to the bottom.

BY MR. POLLACK:

Q. Ms. McDougal, in this document, we see here, under paragraph 3, there's a provision related to indemnification, correct?

A. Yes.

Q. Now, you and Mr. Della Fera had some objections to this provision, correct?

A. Yes.

Q. Was this the only provision in the agreement that you found objectionable?

A. I don't recall any other.

Q. Did you have any objections to the use provision above the indemnification?

A. No.

Q. In fact, the use provision provides that it will be used specifically for what Fera wants to use it for, bioequivalence testing, correct?

A. Yeah, as well as dissolution testing and assay and impurity studies, yes.

Q. Thank you for filling in the blanks.

And in the indemnification provision, if I understand

your testimony correctly, what you found objectionable is the provision in Section V, any product, liability, or other claim arising out of any allegation of injury or death caused by any person's use of Daraprim, correct?

A. I think it was the next one as well. Yeah, V and VI.

Q. So you think it was number VI?

A. It was both.

Q. You're right in your direct testimony, it's number VI, and I apologize.

MR. POLLACK: Justin, can we have the highlighting, and let's correct the record.

Q. So, Ms. McDougal, just so the record is clear, what you objected to in this indemnity provision was VI, "Any liability or other claim, including, but without limitation, injury or death arising from the use of Daraprim," correct?

A. I believe it's V and VI is an issue.

Q. So you had an issue with V as well?

A. Yeah.

Q. And did Fera -- strike that.

Fera didn't just strike out V and VI when it reviewed this agreement, did it?

A. No. As I recall, we struck the entire section.

Q. You just didn't like two provisions, and you struck out the entire thing?

A. Uh-huh.

Q. Is that a yes?
A. Yes.
Q. Okay, thanks.
For today --
A. Yes.
Q. -- like at your deposition, we've got to use full words.
A. Got it.
Q. Thanks.
So that includes everything in here, including things like number III, any breach of this agreement or applicable law by company or its affiliates, right?
A. Well, yeah. It didn't make any sense, really. I mean, it was a purchase agreement --
Q. Well, you struck --
A. How --
Q. You struck that, too, correct?
A. We struck the whole section because, you know, we didn't think -- some of it just didn't make any sense, but what was particularly egregious was V and VI.
Q. Ms. McDougal, if you want to clarify, you'll have an opportunity to do so when the FTC lawyers have their questions for you, okay?
A. Okay.
Q. Thank you.
Now, before striking out this entire indemnity

provision, Fera didn't send this draft of this agreement to any lawyers for review, did it?

A. No.

Q. And after you sent this agreement back with that provision struck in its entirety, that ended the negotiations with Vyera, correct?

A. My understanding was that, again, through the third party, that there was no more communication.

Q. Now, that wasn't Fera's only avenue for Daraprim, was it?

That wasn't the only avenue Fera pursued for Daraprim RLD, correct?

A. No.

Q. I'm not correct, that is --

A. Yes -- can you rephrase the question?

Q. Sure.

Let me say it this way: Fera pursued other avenues to pursue Daraprim RLD other than this purchase agreement with Vyera, correct?

A. We did, yes.

Q. And after you struck the indemnity provision, did you reach out again?

A. I don't recall.

Q. Who was leading the negotiations on this purchase agreement?

A. I don't know what you mean by "leading."

Q. Were you involved in them?
A. I reviewed this purchase agreement, yeah.
Q. And it was your decision and Mr. Della Fera's decision to strike the indemnity provision, correct?
A. Correct.
Q. And you don't recall if there were any other outreaches to Vyera after you sent this back with that provision stricken?
A. Correct.
Q. On December of 2016, Fera was approached by another company, Tanner Pharmaceuticals, with an offer to sell Fera Daraprim RLD, correct?
MR. PERLMAN: Object to form.
THE COURT: That's a yes or a no.
THE WITNESS: Yes.
Q. And in December of 2016, Tanner offered to sell Daraprim to Fera in 25-milligram tablets, in 100 count bottles, for $101,433.09.
Do you recall that?
A. Yes.
Q. When you received that offer, am I correct that your direct report, Genevieve Della Fera, voiced surprise at the cost?
A. I don't know that we were surprised at the cost. It was definitely higher than what was published as the wholesale acquisition cost. So it was a significant markup that we noted.

Q. And the wholesale acquisition cost is, presumably, what Tanner paid for the drug product, correct?

MR. PERLMAN: Objection; speculation.

THE COURT: What was your understanding?

THE WITNESS: I have no idea what -- I didn't think about that.

BY MR. POLLACK:

Q. Did Fera purchase the Daraprim RLD from Tanner -- strike that.

Did Fera seek to purchase the Daraprim RLD from Tanner at the price quoted in December 2016?

A. Did we seek -- we had ongoing negotiations in trying to secure product through them, yes.

Q. You didn't place an order at that time, did you?

A. We did not.

Q. Was that because of price?

A. That was part of it, yes.

Q. At the time, December of 2016, you'd agree with me that Fera had no reason to believe that if it placed an order with Tanner for Daraprim RLD, that Tanner would not have been able to deliver on the product, correct?

A. No, I don't agree.

Q. You don't agree?

Do you recall being asked that at your deposition in this case?

A. No.

MR. POLLACK: Justin, can we bring up Ms. McDougal's deposition, please, at page 84, line 21, to 85, line 2. A little bit above that, so we can establish a time frame, so go with 14.

BY MR. POLLACK:

Q. Here, you're being asked about Tanner's ability to sell Daraprim RLD in December of 2016. The question the attorney asked you: Well, at this point, you hadn't had an experience with Xcelience yet, so I'm asking you, at this point, in December of 2016, did you have any basis to believe that you could not -- what's that?

You answered: I'm sorry, yeah, thank you for orienting me with the time.

Sorry, the question goes on --

THE COURT: Slow down.

MR. POLLACK: You're right.

BY MR. POLLACK:

Q. -- did you have any basis to believe they couldn't have supplied it if you had ordered it at that time?

And your answer was: No.

A. Yeah, the same kind of issue, so, yes, I changed my answer.

At that time, we didn't think that, you know, they couldn't supply it, necessarily, although we did have some feedback from --

Q. So the answer was no?
A. Yes.
Q. You had no reason to believe that they couldn't deliver in December of 2016?
A. Correct.
Q. But you didn't place an order at that time?
A. No.
Q. That is, no, you did not place an order?
A. Correct.
Q. Thank you.

Now, after that first parlay by Tanner, Tanner reached out again, on January 11th, 2017, with a second offer to sell Daraprim RLD to Fera; am I right?
A. Yes.
Q. And am I also right that at this time, in January of 2017, Tanner disclosed to Fera that it had available Daraprim 25 mg tab, 100, meaning 25-milligram, manufacturer - Turing, package — 100 tablets, or 100 tabs, quantity — seven bottles, price per bottle — $177,628?
A. What was the time frame?
Q. January 11, 2017.
A. I don't really recall, but I'm sure you're reading some -- I don't recall.
Q. Well, perhaps there's a document I can show you to refresh your recollection.

Ms. McDougal, did you complete written responses to a civil investigative demand in this case?

A. Yes.

Q. That's a yes?

A. Yes.

Q. I'm hard of hearing. If I don't hear you, it's not because of you, it's probably because of me, okay?

A. Okay.

Q. I don't want you to feel bad about that.

Were you accurate in your responses to the civil investigative demand?

A. Yes.

MR. POLLACK: Justin, can we pull up Exhibit DX 281, please.

Q. Ms. McDougal, take a moment to review just the top level of this document and tell me if you recognize it as one of Fera's responses to the FTC's civil investigative demand.

(Pause)

A. Okay.

Q. Is the "okay" meaning this is your response that you wrote to a civil investigative demand?

A. Yes. It's part of it, yes.

MR. POLLACK: Justin, if we could turn to page 3, 13651 at the bottom, and blow up everything from on January 11, 2017, to the bottom.

Q. Ms. McDougal, take a moment to read that and see if it refreshes your recollection as to what Tanner had offered Fera in January of 2017.

A. Okay.

I'm finished reading it, and, yes, I recollect this.

Q. Does the document accurately reflect what I just asked you, that in January 11, 2017, Tanner had offered to Fera the opportunity to purchase 25-milligram tabs of Daraprim in 100-count bottles, up to seven bottles, at a price per bottle of $177,628 per bottle?

A. Yes.

Q. Or, alternatively, 30-count bottles of 25-milligram tabs, up to six bottles, at the price of $67,641.70, correct?

A. Correct.

Q. Does the document also accurately reflect that Fera again challenged the pricing of these Daraprim bottles with Tanner?

A. Yes.

Q. And did Fera seek to negotiate a discount on the price offered by Tanner based upon the number of bottles to be purchased?

A. Yes.

Q. And did Tanner actually offer Fera a discount?

A. It says here they did, yes.

Q. Okay.

Does this document also reflect your recollection that

Tanner offered Fera a discount that if it was to purchase four 100-count bottles, that there would be a 2.8 percent discount?

A. Yes.

THE COURT: Is DX 281 in evidence, or are we using it to refresh recollection? What is its status?

MR. POLLACK: It's not in evidence, your Honor.

THE COURT: Okay.

MR. POLLACK: Should we take it down?

THE COURT: No. I just -- for the record, then, a lot of the information that's been read out of the document is not part of the evidentiary record. That's fine. I just wanted to make sure.

BY MR. POLLACK:

Q. Well, Ms. McDougal, let me ask you, independent of this document, is it true that Fera, after receiving the price quote, negotiated a discount?

A. Yes.

Q. This document refreshed your recollection, correct, of the bottle numbers -- the number of bottles and the price at which Tanner had offered them to you, correct?

A. Yes.

Q. And the information that you gave to me is truthful and accurate as to the offer that Tanner made on January 11, 2017, correct?

A. Correct.

Q. And the same would be true about the discount that Tanner offered, correct?

A. Correct.

MR. POLLACK: We can take that down, Justin. Thank you.

Q. And after Tanner offered Fera a discount of 2.8 percent, did Fera then agree to purchase bottles of Daraprim from Tanner?

A. No.

Q. Was the concern that the price was still too high?

A. That was part of the concern, yes.

Q. And because of that, Fera made the business decision not to purchase Daraprim RLD when offered it by Tanner on January 11, 2017, correct?

A. Correct.

Q. And it also made the business decision not to purchase it, when offered the opportunity to do so, in December of 2016, correct?

A. Correct.

Q. After getting this proposal in January, did Fera also seek to negotiate an arrangement whereby it would not have to prepay the entire price of Daraprim RLD to Tanner?

A. Yes.

Q. Was the arrangement that Fera was able to negotiate with Tanner a 60/40 split?

A. I don't recall. I don't really understand the question.
Q. Sure. Maybe I have a document to help us with this.
MR. POLLACK: Justin, can we pull up Exhibit 285, please.
THE COURT: Is that DX?
MR. POLLACK: No, your Honor. This one is not in evidence, it's not on anyone's list. I'm going to use it to refresh recollection.
THE COURT: So is this DX or GX?
MR. POLLACK: It would be DX 285, but, again, it's not on our exhibit list. You won't find it in the records you have. I can hand up a copy --
THE COURT: It's not necessary. I just wanted, for clarity of the record, whatever we're referring to.
MR. POLLACK: All right. Thank you, your Honor.
And, Justin, if you could turn us to page 304 of the document, please, and highlight the bottom-most email.
BY MR. POLLACK:
Q. Ms. McDougal, I'll ask you to read this to yourself and let me know if it refreshes your recollection of the payment arrangement that Fera negotiated with Tanner.
THE COURT: So, refreshing recollection means that you're just supposed to testify based on your current recollection. So you can read this to yourself, and it either will bring back a memory or it won't.

(Pause)

THE WITNESS: I don't specifically remember this.

BY MR. POLLACK:

Q. You don't remember this?

A. Not specifically.

MR. POLLACK: Take that down. Thank you.

Q. But you do recollect negotiating some form of split with Tanner?

A. No. The thing I do remember is the -- sort of a request, that last bullet, for the audited financials of the company, because I know that was a concern. But the split and --

Q. But do you recollect a negotiation with Tanner over how much Fera would be willing to prepay upfront?

A. I don't remember the specifics. I know we had a concern about paying the fees in total because we were not familiar with Tanner and just some of the troubles that we had prior.

Q. Now, Tanner came back a third time, in September of 2017, with a third offer to sell Daraprim RLD to Fera, correct?

A. I don't really recall the time.

MR. POLLACK: Let's bring up the CID again, please, Exhibit 281. And, Justin, if you could highlight the third paragraph on page 4.

Q. Ms. McDougal, I'll ask you to read your response to the FTC on behalf of Fera, and tell me if this refreshes your recollection as to the question I just asked you and whether

Tanner offered Daraprim to Fera on September 28th, 2017.

A. Okay, I see it. I'm refreshed.

Q. And does this?

A. Yes.

Q. So, correct, Tanner did offer again to sell Daraprim to Fera in September of 2017?

A. Yes.

Q. Thank you.

MR. POLLACK: You can take that down.

Q. At this time, was one of the ongoing issues for Fera that Tanner wanted payment upfront?

A. Yes.

Q. In your written direct, you state that Tanner eventually agreed to an escrow agreement with Fera, correct?

A. Yes.

MR. POLLACK: Can we bring up Exhibit DX 291, please. And can we go to page 4 of the document, please. I would like to highlight and bring up the bottom email, please.

Q. Ms. McDougal, this is an email from Genevieve Della Fera.

Do I understand her to report directly to you at the time?

A. Yes.

Q. And you're copied here, correct?

A. Correct.

Q. And the email is to Richard Lambie at Tanner Pharma,

correct?
A. Correct.
Q. Do you recall this email?
A. Not this specific email, no.
Q. Do you recall sending emails to Tanner regarding Daraprim's sourcing options?
A. Yes.
Q. In the email, Ms. Della Fera writes, "Dear Richard" --
THE COURT: Excuse me. Is this in evidence?
MR. POLLACK: I was going to say one more thing to lay a foundation for it and move it, but, your Honor, I would move for the admission of this document, DX 291.
MR. PERLMAN: No objection, your Honor.
THE COURT: Received.
(Defendant's Exhibit 291 received in evidence)
MR. POLLACK: Thank you, your Honor.
BY MR. POLLACK:
Q. Ms. McDougal, we see here that Ms. Della Fera is sending Mr. Lambie an escrow agreement with Fera's wiring instructions, correct?
A. Yes.
Q. And that was on October 12, 2017, correct?
A. Yes.
Q. Now, do you recollect the occurrence of that, sending the escrow agreement to Tanner Pharma?

A. Yes.
Q. Was that an escrow agreement, since it's coming from Ms. Della Fera, that someone at Fera drafted?
A. No.
Q. Did it contain Fera's requested edits and changes?
A. I believe so, yes.
Q. Did Ms. Della Fera have your authorization to send the escrow agreement to Tanner?
A. Yes.
MR. POLLACK: Justin, let's go up to the next email in the chain, just above this one.
Q. And we see here, Ms. McDougal, Mr. Lambie writes back on October 13, 2017, saying, "Hi Genevieve. Please find the completed form attached," correct?
A. Yes.
Q. So am I correct that Tanner signed and returned the escrow agreement that Ms. Della Fera sent to them?
A. I don't know that for sure. I don't know what's attached and what form he's referring.
Q. You said, in your written direct, that Tanner eventually agreed to an escrow agreement, correct?
A. They did agree.
Q. Was it to the form that you requested?
A. I don't remember how far along the actual document specifically got through, whether they signed or not, but I

know that we spent time with them on it.

Q. And perhaps you're right, it says here -- oh, no, never mind.

If we go up to the next email, on page 3 of 7, Ms. Della Fera responds to Mr. Lambie saying, "Hey, Richard. We're good with just a scanned copy of the PDF. We don't need the DocuSign. Would you please initiate execution of the document."

Do you see that?

A. I do.

Q. She didn't raise any issue with the form of the document that Mr. Lambie sent back, correct?

A. Not at this time.

MR. POLLACK: If we go up to page 1, please. No, the bottom, please.

Q. We see here that Mr. Lambie writes back on October 17, 2017, "Dear Genevieve: Please find attached our executed document for counterexecution."

Does that indicate to you that Tanner signed the agreement that Ms. Della Fera sent over?

A. It seems to indicate that, yes.

Q. But Fera never countersigned the escrow agreement sent to Tanner; is that right?

A. That's right.

Q. And Fera never placed an order with Tanner Pharmaceuticals

for the purchase of Daraprim RLD, correct?
A. Correct.
Q. Next, in January of 2018, approximately three months after Tanner signed Fera's escrow agreement, Fera placed an order for two bottles of Daraprim with another procurement firm, Reliant Specialty LLC, correct?
A. Correct.
Q. Am I also correct that Fera structured that deal with 50 percent payment upfront, 50 percent upon delivery?
A. Correct.
Q. And Fera received the two bottles from Reliant, correct?
A. Correct.
MR. POLLACK: Can you bring up DX 121, please. And highlight the first two emails. Thank you.
Q. Ms. McDougal, I'll be brief on this, because I've covered it with Mr. Della Fera, but on February 12, 2018, Mr. Valiveti wrote to you and Mr. Della Fera saying, "Dear Susan: Please let me know if you need any additional quantity on Daraprim," correct?
A. Yes.
Q. And in the next email, on the same day, you responded, "Thank you, Satya. We are good for now"?
A. Yes.
MR. POLLACK: You can take that down, please.
Q. When you declined to purchase additional Daraprim RLD from

Mr. Valiveti and his company, Reliant, you knew that, like anything else in life, there's never a guarantee that a product that's available one day is going to be available the next, right?

MR. PERLMAN: Object to form of that question.

THE COURT: Sustained.

BY MR. POLLACK:

Q. Ms. McDougal, did you know, when you declined Mr. Valiveti's invitation to purchase more Daraprim, whether or not he would still have it in stock if you wanted to purchase it at a later date?

A. No, not definitively.

Q. And the reason Fera didn't seek to purchase more Daraprim RLD from Mr. Valiveti was, in your words, to derisk the investment by purchasing only two bottles, correct?

A. Correct.

Q. And you and Mr. Della Fera, at the time, were hopeful that you would be able to negotiate your way through a waiver with the FDA, correct?

A. So we're at, what, February of '18 now? I don't know if that was definitely our plan at that time. I know that we knew that that would be likely something we would have to pursue if we couldn't get more product or, you know, just -- that's it.

Q. Are you saying you don't remember, or are you disagreeing with me?

MR. PERLMAN: Object to the form of that question.

THE COURT: Sustained.

THE WITNESS: Can you repeat the question?

MR. POLLACK: I'll move on.

Your Honor, may I step away from the podium for one moment to consult with my colleagues?

THE COURT: Sure.

Just put your mask back on. Thanks.

MR. POLLACK: Thank you for that reminder.

(Pause)

BY MR. POLLACK:

Q. Now, I want to turn to the issue of contract manufacturing.

So we determined already that Fera had contracted with Xcelience, correct?

A. Correct.

Q. And that was in July of -- I'm sorry. What was the time frame for that contract; do you recall?

A. December of '16.

Q. And by July 2017, Fera terminated its contract with Xcelience, correct?

A. It may have been a little bit later than that, but that's the general time frame.

Q. And that was because Fera had lost faith in Xcelience because it could not acquire Daraprim RLD; is that right?

A. We just couldn't move forward with them without the RLD at

that time.
Q. And that was -- you didn't have to terminate Xcelience; that was a business decision by Fera, correct?
A. Correct.
Q. To manufacture generic Daraprim, Fera then had the contract with a new CRO or CMO? I'm not sure of the correct term. Maybe you can tell me.
A. We had to find somebody else to work with to develop and manufacture the product, yes.
Q. And in November 2017, Fera contracted with a firm named Latitude, correct?
A. What was the time frame again?
Q. November 2017.
A. That sounds right, yes.
Q. If I understand it right, Xcelience could both develop the manufacturing process for generic Daraprim and then also create the finished product for, among other things, bioequivalence testing, correct?
A. Yes.
MR. PERLMAN: Object to form.
THE COURT: Overruled.
BY MR. POLLACK:
Q. But Latitude could only do one of those two things, it could only develop the manufacturing process, right?
A. Correct.

Q. And Latitude, using API manufactured by your supplier, which, for purposes of this case, we're calling API Company No. 1, using that API, Latitude did not finish developing a prototype for generic Daraprim until, approximately, August of 2018; is that right?

A. Correct.

Q. At that point, Fera needs to bring in another contracting organization to actually produce the finished product, correct?

A. Correct.

Q. And am I right that in October of 2018, Fera brought in a firm called Rivopharm?

A. Correct.

Q. So Fera is now using Latitude and Rivopharm to do the job that Xcelience was able to do by itself?

A. Xcelience wasn't able to do the job, so while they had capability, they were not able to fulfill the task of formulating and manufacturing a generic Daraprim.

Q. Because they didn't have the RLD?

A. Correct.

Q. And you didn't have the RLD until -- you didn't have any RLD until after you terminated Xcelience, correct?

A. Correct.

Q. And Rivopharm finished manufacturing generic Daraprim for Fera in April of 2019, correct?

A. It was around that time frame, yes.

Q. And at this point in time, am I also correct that Fera was still working its way through waiver applications with the FDA?
A. Yes.
Q. Switching topics one more time, and I'm winding things up here, you've never worked for the FDA, correct?
A. No, I have not.
Q. In your written direct, you say that it is unlikely -- excuse me, let me make sure I pull it up, so we're all on the same page.

You say, "If we had used" -- and I'm at paragraph 41, if you'd like to follow along. It's on page 13.

A. Okay.
Q. You say, "If we had used Fukuzyu," and "we" meaning Fera, correct?
A. Correct.
Q. -- "as our API supplier, I find it very unlikely that the FDA would raise this issue, given that it was already familiar with Fukuzyu's manufacturing process."

Did I read that correctly?

A. Yes.
Q. And the issue that we're talking about here is what?
A. When we had submitted our ANDA, the FDA had questions about our API supplier's process, essentially.
Q. So I understand correctly, Fera reached out to Fukuzyu at the beginning of its efforts to develop a generic Daraprim

product, correct?
A. Correct.
Q. Am I correct that that occurred in early 2016, or late 2015?
A. Correct.
Q. I believe, again, it was your direct report, Genevieve Della Fera, that reached out to Fukuzyu, correct?
A. Correct.
Q. And she used an email address she found online?
A. Correct.
Q. And she received no response back from Fukuzyu, correct?
A. Correct.
Q. When Fera received no response back from Fukuzyu, it made the business decision to go with another company, API Company No. 1, correct?
A. Correct.
Q. And I understand, from your written testimony, that later, in September of 2017, through your consultant, Mr. Conte, Fera again reached out to Fukuzyu; is that correct?
A. Yes.
Q. And, again, if I understand your testimony, the reason you reached out to Fukuzyu was to purchase API to use as a reference to test API Company No. 1's API against, correct?
A. Correct.
Q. And, at this point in time, by the way, in September of

2017, we're basically just a month out from when API Company No. 1 will finish its API batch, correct?

A. Correct.

Q. And we're now more than a year into your company's relationship with API Company 1, correct?

A. Yes.

MR. POLLACK: Justin, can we pull up Exhibit 3106 -- GX 3106, please.

And, your Honor, I believe this is in evidence, but, if not, I'll move it into evidence.

THE COURT: Any objection?

MR. PERLMAN: No, your Honor.

THE COURT: Received.

(Government's Exhibit 3106 received in evidence)

BY MR. POLLACK:

Q. Ms. McDougal, can you tell me if you've seen this document before?

A. Yes.

Q. Does this document reflect the payments that Fera made to API Company 1 to develop pyrimethamine API?

A. Yes.

Q. If we look here, prior to --

A. Excuse me, I just want to interject.

There's also some payments to a consultant firm we use sprinkled through this, but you can see where API 1 payments

were made as well.

Q. I see.

So which -- ah, so anything that's not API 1, the one that's with the consult, that would be your consulting firm?

A. Right, that helped us work through the technicalities of the API.

Q. If we look at this document, prior to September 2017, there were five payments to API Company No. 1, correct?

A. Correct.

Q. And I know you don't have a calculator with you. I've added them up; I'll represent to you they total $233,500.

Any reason to disagree with me on that?

A. That sounds right.

Q. And that's if we look at the total research and development expenses line down at the bottom of $518,025.50, that's roughly half of what you would ultimately pay API Company No. 1 just for R&D, correct?

A. Correct.

MR. PERLMAN: Object to form.

THE COURT: Overruled.

MR. POLLACK: Let's bring up Exhibit GX 3192, please.

3192.

Take that down, please. It's not in evidence.

Ms. McDougal, I believe that is all the questions I presently have for you. I want to thank you again for your

time and coming out to answer my questions today.

MR. PERLMAN: Bryce, could I have you put GX 3106 back up. It's the document we were just looking at.

(Continued on next page)

REDIRECT EXAMINATION

BY MR. PERLMAN:

Q. Ms. McDougal, do you recall discussing GX-3106 with Mr. Pollack?

A. I do.

Q. I believe you testified something to the effect -- let me rephrase that question.

Do you know the date of this document?

A. It says May 30, 2019.

Q. Did Fera spend more money on its API after May 30, 2019?

A. Yes.

Q. Do you know roughly how much more?

A. Another ultimately I think another $500,000 in total. So for a total of a million.

MR. PERLMAN: Thank you, your Honor. I have no more questions.

THE COURT: Any recross?

MR. POLLACK: No, your Honor. Thank you.

THE COURT: Give me just one minute, Ms. McDougal.

There were two requests from Fera for Fukuzyu pyrimethamine, the API ingredient at issue here, and I believe you've just testified that the second request that Fera made was in September of 2017. Did I catch that right?

THE WITNESS: Yes.

THE COURT: And did Fukuzyu agree to provide

pyrimethamine to Fera in September of 2017?

THE WITNESS: No.

THE COURT: And if Fukuzyu had agreed in September of 2017 to supply the API, what impact do you believe that would have had on Fera's plans to develop this generic alternative to Daraprim?

THE WITNESS: I think that ultimately with regards to the FDA's review, I think it would have -- we had a lot of questions on our API process from the FDA. One of the questions -- a lot of the questions the FDA had for us when we submitted the ANDA was with regard to the API, and those questions came right basically at the time COVID hit, so that delayed our approval significantly. I don't think that if we used Fukuzyu API those questions have arisen because that material was already used in FDA-approved currently marketed product. I think that was number 1.

I think number 2, part of the reason why we went back to Fukuzyu also was to be able to compare the innovator or their API that was being used in Daraprim to ours to understand, you know -- to characterize it as best we could versus the innovator. I think -- I think at the end of the day we were a bioequivalent, so it was fine. But we may have seen some things that maybe would have sped our development along as well.

I think we would have been able to get that API. We

may have pivoted to the Fukuzyu and then that would have made a more efficient approval process with FDA, and it may also have improved at that point our timeline to ultimately submitting to the FDA.

THE COURT: In September of 2017, however, when you made that request of Fukuzyu, you did not at that time have an ANDA submitted to the FDA and, therefore, you did not yet have the questions from the FDA.

So placing yourself back in September of 2017 and not able to look into the future, do you believe you would have pivoted if Fukuzyu had been willing to provide you with the API then, knowing how much you had already invested in another company, which we are calling company number 1, in their process of developing the API for you?

THE WITNESS: Yes, I believe we would have.

THE COURT: And why?

THE WITNESS: Again, it was -- even though we had invested that amount of money, it was understood by us that, again, this was an API that was currently approved on the U.S. market and it would have derisked our whole program as far as the API was concerned.

THE COURT: Counsel, do you have any additional questions for this witness, given the questions I have just put to her?

MR. PERLMAN: No, your Honor.

MR. POLLACK: Yes, your Honor. Thank you.

I'm sorry, your Honor. Forgive my delay.

RECROSS EXAMINATION

BY MR. POLLACK:

Q. Ms. McDougal, API purchased for use as a reference comparator, purchased for comparator testing, could that be used to manufacture a batch of generic Daraprim?

A. It depends how much is purchased and what a batch is requiring.

Q. Would you purchase a full batch just for purposes of comparator testing? You wouldn't, would you?

A. I don't know. I can't answer that.

MR. POLLACK: At this time I would like to bring up Exhibit 3192, please.

THE COURT: Is that GX?

MR. POLLACK: It is. I'm sorry, your Honor. GX-3192.

Q. Ms. McDougal, if I understand your written testimony, your communications with Fukuzyu were being conducted through a consultancy called Charkit, correct?

A. Yes. They were a broker.

Q. They were acting on your behalf?

A. Correct.

Q. Now, comparator testing, is that using API for human use?

A. I don't know -- I don't understand your question.

Q. When you're running a comparator test, that's testing API

against API to determine equivalency, correct?

A. You characterize API, how -- its security profile.

Q. You are trying to determine --

A. Compare it, yes.

Q. You are trying to determine whether or not company number 1's API is chemically or molecularly equivalent to Fukuzyu's API. Is that what the comparator test is? Am I understanding things correctly?

A. They are both molecularly pyrimethamine, and I'm not a chemist. But the idea is just to understand, again, like say impurities and peeks of the impurities. They retain at certain rates and they can vary and that can have, I guess, implications into ultimately how it can be used in a finished product.

Q. In other words, it's not being ingested by a human being during that testing, correct?

A. Correct.

MR. POLLACK: Your Honor, I would at this point move in GX-3192.

MR. PERLMAN: I believe it's already in evidence, your Honor.

MR. POLLACK: Then it's in.

If we can go to page 2 of the document, please. Can we blow up the top-level e-mail, please.

Q. Ms. McDougal, we see here there is an individual named

Panos Yannopoulos writing an e-mail to Mitsuaki Abe.

Mr. Yannopoulos is he the representative from Charkit?

A. Yes.

Q. Did you communicate directly with him, Mr. Panos Yannopoulos, about negotiations with Fukuzyu?

MR. PERLMAN: Your Honor, this is getting beyond the scope of your questions, I believe.

MR. POLLACK: I am going to tie it together. I'll permit it.

It's not very much longer, your Honor. I promise.

Q. Who communicated with Mr. Yannopoulos?

A. Our consultant, Gary Conte.

Q. Did Mr. Conte pass Mr. Yannopoulos' messages along to you?

A. Yes.

Q. Did you have input into Mr. Yannopoulos' communications to Fukuzyu?

A. Only if there were questions being asked by Fukuzyu that needed to be answered.

Q. One of the things that Fukuzyu wanted to know was whether the API would be for human use in the United States, correct?

A. Yes.

Q. Did you discuss that with Mr. Conte?

A. Yes.

Q. Did Mr. Conte pass along your concerns to Mr. Yannopoulos?

MR. PERLMAN: Object to the form of that question.

MR. POLLACK: Withdrawn.

THE COURT: Counsel, I think we are way beyond the scope. I was waiting for you to try to link it up, but I can't see the linkage.

MR. POLLACK: I'll do it in the next question, your Honor.

Can we go to the last e-mail, please, on the bottom of the page.

Q. The one I'm focused in on is, Ms. McDougal, is 2017, 12/21, at 11:40 from Panos Yannopoulos saying: OK. Abe-SAN. I've got all our ducks in a row and addressed every concern. Now all I need is a C of A and the sample in question, and we could revert with a firm PO for 20 grams at U.S. dollars, $200 a gram for shipment to customer, destination address in Argentina. We can also confirm our adherence to the statement required regarding sales of the API will not be used to make pyrimethamine drug product for human use.

THE COURT: Counsel, how is this of assistance to you? This is Fukuzyu refusing to provide API for human use in America.

MR. POLLACK: That is Mr. Yannopoulos confirming that Fera is not looking to source API for manufacturers. It's looking for a comparator, not for human use.

THE COURT: Forget the document. Ask the witness questions.

MR. POLLACK: Your Honor, I rest.

THE COURT: No, counsel. I'm letting you continue. But just try to get her recollection. If you start with that before you go to the document.

Q. Ms. McDougal, is it the case that your company was not looking for API to manufacture Daraprim from Fukuzyu? You were looking for a reference sample as you told me earlier today, correct?

MR. PERLMAN: Object to the form of that question.

THE COURT: Sustained to form. But please place your question, counsel.

Q. Ms. McDougal, isn't it correct, as you told me earlier, that your company was looking for a reference sample for API from Fukuzyu, correct?

A. I said that, but I also said we were trying to open up communication with Fukuzyu to pursue a potential relationship as a supplier. So the feedbacks we were getting made it clear that that wasn't going to be viable, but that was also part of our intent.

MR. POLLACK: Your Honor, no further questions.

THE COURT: Thank you.

Any further redirect?

MR. PERLMAN: No, your Honor.

THE COURT: You may step down.

(Witness excused)

THE COURT: Next witness.

MR. PERLMAN: Your Honor, if I may, I just have a couple of exhibits that were in these affidavits that I believe we reached resolution on with defendants. Plaintiffs would like to move these in not for the hearsay purpose but just for the truth of the matter asserted in these exhibits.

THE COURT: Not for the truth of the matters contained therein, but simply for the fact that these communications were made at around those times?

MR. PERLMAN: Yes, your Honor. In particular, the first one is GX-3246. It attaches a news article. I believe that was the focus of defendant's objection.

THE COURT: Any objection to the receipt of GX-3246 received not for the truth of the matters stated therein?

Hearing no objection, it is received.

(Government Exhibit 3246 received in evidence)

MR. PERLMAN: I'm sorry, your Honor. Should I address this question?

THE COURT: Sure. Why don't you consult, counsel. No need to rush.

MR. POLLACK: I think what Mr. Perlman said was that this document comes in not for its truth. We agree.

MR. PERLMAN: I believe the other document was GX-3192, which was the e-mail chain that you just showed Ms. McDougal, so I think that's already in evidence, but I just

wanted to make sure.

THE COURT: Received. If not already formally on the record, the parties understand it is received. It is received by me.

(Government Exhibit 3192 received in evidence)

MR. PERLMAN: Thank you, your Honor.

THE COURT: Did you have another witness to call?

MR. MEIER: Thank you, your Honor. Because these examinations ran quite a bit longer than we had anticipated, we had to do a little bit of reconfiguring of the schedule. We had told your Honor that we would call Howard Dorfman next, but we had to move him to another day.

We would now call, and I am not sure how to pronounce the name, but I will do my best, Abhishek Mukhopadhyay with Dr. Reddy's, and my colleague, Leah Hubinger, will be responsible for the government's examination of this witness, your Honor.

THE COURT: Would the witness please approach. If you could take the witness stand and remain standing.

ABHISHEK MUKHOPADHYAY,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

THE COURT: You're about to be shown a document by counsel, which I believe is Government Exhibit 809.

MS. HUBINGER: That's correct, your Honor. May I approach?

THE COURT: I would ask you to look at page 12, the last page of that document, and ask if you authorized an electronic signature, your electronic signature to be placed on the last page?

THE WITNESS: Yes.

THE COURT: Before giving that authorization, did you read this document with care?

THE WITNESS: Yes.

THE COURT: And do you swear to the truth of its contents?

THE WITNESS: Yes.

THE COURT: Is there any objection to receipt of GX-8009?

MR. CASEY: Yes, your Honor. We have just a few objections to some of the paragraphs, your Honor.

We object to the admission of paragraphs 13 and 14 on the basis of Rule 602 of the Federal Rules of Evidence. Those paragraphs discuss technical details regarding Bactrim in paragraph 13 and compounded pyrimethamine in paragraph 14.

We don't believe there has been a foundation established for the witness' knowledge about those two topics.

We also have objections to paragraphs 28.

THE COURT: If it's a separate objection, can we take them one at a time?

MR. CASEY: Sure.

THE COURT: Thank you so much.

Paragraphs 13 and 14. Give me a second. Thank you.

The objection is overruled. I am looking at the description of the witness' job at Dr. Reddy's and, in particular, paragraph 5.

Next.

MR. CASEY: Your Honor, there are three objections, all on hearsay grounds and those paragraphs are paragraphs 28, 32, and 33. In each of those paragraphs there is reference to statements by other people. Some of them within Dr. Reddy's and some of them outside of Dr. Reddy's. All of those statements are hearsay. We object on hearsay grounds.

THE COURT: I assume they are being offered for the fact they were stated to this witness and to explain what he did next or didn't do next. Is that right?

MS. HUBINGER: Yes. That's correct. He is relying on those statements when he is making his own decisions and suggestions about how Dr. Reddy's should source RLD.

THE COURT: Your objection is well taken, but I will receive these statements not for their truth but for the fact that they were stated.

MR. CASEY: Thank you, your Honor.

THE COURT: With that, GX-8009 is received.

(Government Exhibit 8009 received in evidence)

THE COURT: Cross-examination.

CROSS-EXAMINATION

BY MR. CASEY:

Q. Good afternoon, Dr. Mukhopadhyay.

A. Good afternoon.

Q. Am I pronouncing your last name correctly?

A. Yes.

Q. My name is Christopher Casey and I'm representing Mr. Shkreli in this trial. I'll be questioning you today.

I want to ask you, first, some questions about the affidavit that you just swore to and has been entered into evidence.

First, Dr. Mukhopadhyay, if I could direct your attention to paragraph 17 and 18. They would be on page 6.

A. Yes.

Q. If you look at paragraph 17, the heading before the paragraph says: Cerovene search for new API supplier. Do you see that?

A. Yes.

Q. The paragraph reads: The business development team's main concern was Cerovene's search for an alternative API supplier. A generic company needs to locate an API supplier with an active U.S. DMF to make an FDA-approved drug product. Alternatively, generic companies like Dr. Reddy's could develop their own API in house, although the process of doing so can take years. That's paragraph 17.

Paragraph 18 says: Cerovene had submitted its ANDA to the FDA using API from Ipca. Before I began discussions with Cerovene, the FDA had placed Ipca on import alert, which meant that Cerovene would not be able to use Ipca's API. Cerovene had received a complete response letter from the FDA that indicated that's ANDA was ready for approval, except for the compliance status of its API supplier.

That was your testimony, correct?

A. Yes.

Q. Dr. Mukhopadhyay, you don't have any personal involvement in API sourcing at Dr. Reddy's, correct?

A. No.

Q. No, meaning you do our don't?

A. I don't.

Q. You do not. Is that your answer?

A. Yes.

Q. Thank you.

Then moving down to paragraph 20, that paragraph reads: Through these interactions with Cerovene, I learned that Cerovene first attempted to source API from Fukuzyu based on my knowledge of generic drug product development. Fukuzyu would have been the best option after Ipca because it had an active U.S. DMF. After significant delays, though, Fukuzyu eventually refused to supply Cerovene.

That was your testimony in paragraph 20, correct?

A. Yes.

Q. You have no independent knowledge of the negotiations between Cerovene and Fukuzyu other than what Cerovene told you, correct?

A. Yes.

Q. You have no independent knowledge of the negotiations between Cerovene and RL Fine, correct?

A. Yes.

Q. In fact, you have never even seen the API supply contract between Cerovene and RL Fine, correct?

A. Yes.

Q. If I could move to paragraph 25. The heading there is: Difficulties obtaining reference listed drug (RLD) required for additional bioequivalence testing delayed the generic Daraprim project.

Plaintiff 25 says: In December 2017, the FDA notified Cerovene that it needed to perform additional bioequivalence studies using RL Fine's API. To perform these studies, I understood that Cerovene would be required to obtain brand-name Daraprim, also referred to as the reference listed drug, RLD. I expected that it would take only a few weeks to obtain Daraprim RLD. Based on my knowledge of generic drug development, I anticipated that completing the bio studies would take three to four months.

That was your testimony, correct?

A. Yes.

Q. But, in fact, you didn't know how long it would take to obtain Daraprim RLD because sourcing RLD was Cerovene's responsibility, not Dr. Reddy's, correct?

A. Yes.

Q. Now, just moving ahead to paragraphs 39 and 40, I am not going to read the whole paragraph. But the heading on this is about Dr. Reddy's distribution of generic Daraprim. I'll just read from the sentence that begins: Dr. Reddy's chose to sell generic Daraprim in an open distribution model, which includes using large drug wholesalers, such as Cardinal and McKesson, as well as various specialty pharmacies.

The distribution strategy for generic Daraprim was designed to encourage and enable broader access to the patients, who could purchase the drug in various pharmacies rather than one specific store. Hospitals and group purchasing organizations could also obtain generic Daraprim directly from a wholesaler or the manufacturer.

That was your testimony in paragraph 39, correct?

A. Yes.

Q. In paragraph 40 you state: I am not aware of any discussions concerning restricting the distribution of pyrimethamine. I am not aware of discussions concerning potential risks associated with product safety, product liability, or product quality that would indicate that open

distribution would not be appropriate for generic Daraprim.

That was your testimony in paragraph 40, correct?

A. Yes.

Q. To be clear, you don't have any personal involvement with distribution at Dr. Reddy's, correct?

A. Yes.

Q. You were not personally involved in the decisions about how generic Daraprim would be distributed, correct?

A. Yes.

Q. So you don't know what the people who made the decisions about generic Daraprim's distribution considered in making that decision, correct?

A. Yes.

Q. Doctor, I'd like to move on then from your affidavit and talk about the timeline of events that is in your affidavit. I am not going to specifically refer to the affidavit, but -- I will, but what I want to do is just get some dates down, just so I understand the timeline. OK?

A. Sure.

Q. In March of 2016, Dr. Reddy's learned about Cerovene's efforts to develop a generic Daraprim product, correct?

A. Yes.

Q. At that time Dr. Reddy's learned that Cerovene had already filed an ANDA for a generic form of Daraprim, correct?

A. Yeah.

Q. Dr. Reddy's then learned that Cerovene's ANDA had used pyrimethamine API from Ipca, correct?
A. Yes.
Q. Following the filing of Cerovene's ANDA, the FDA had placed Ipca on an import alert, correct?
A. Yeah.
Q. On January 3, 2017, Dr. Reddy's development and supply agreement with Cerovene was signed, correct?
A. Yes.
Q. Several months later, on April 2, 2017, Cerovene submitted its major amendment with the FDA identifying RL Fine as its new API supplier, correct?
A. Yes.
Q. Then in December 2017, the FDA issued Cerovene a complete response letter, correct?
A. Yes.
Q. In that complete response letter the FDA said that Cerovene needed to repeat the bioequivalence testing using fresh tablets manufactured by RL Fine versus unexpired Daraprim tablets. Is that correct?
A. Yes.
Q. This meant that Cerovene had to get new supplies of Daraprim RLD to conduct the bioequivalency testing, correct?
A. Yes.
Q. At the time that Cerovene filed its major amendment with

the FDA, which is in April of 2017, which identified RL Fine as its new API supplier, there was a risk that the FDA would not accept the bioequivalence testing results that Cerovene had previously submitted and would require new bioequivalence testing, correct?

THE COURT: Excuse me just one second. I want to make sure I'm following your timeline.

Now we are back in April.

MR. CASEY: Yes. I'm sorry, your Honor. I should have flagged it.

THE COURT: Fine.

MR. CASEY: Talking about April of 2017.

THE COURT: We are back at April. It's the time the amendment was filed.

MR. CASEY: Correct.

THE COURT: Great.

Q. Do you want me to repeat the question, Doctor?

A. Yes.

THE COURT: No.

Q. I'm happy to.

A. Go ahead.

Q. As of the time that Cerovene filed its major amendment with the FDA, which was in April of 2017, identifying RL Fine as its API supplier, there was a risk that the FDA would not accept the bioequivalence testing results that Cerovene had previously

submitted and would require new bioequivalence testing, correct?

A. When you say risk, whose risk is it? Is it risk as identified by Dr. Reddy's or by Cerovene?

Q. The question is, was there risk, risks to Dr. Reddy's?

A. So I would say there is always risk. In this case this was an immediate release product.

THE COURT: Excuse me. I'm sorry. I forgot to tell you. You may remove your mask. We have tested the ventilation system in this courtroom. When you are speaking from that location, you can be unmasked. There is a full air exchange at least every 10 minutes. Also, counsel at the podium can remove their mask. Sorry for not telling you.

A. We understood that this was an immediate-release product, and for an immediate-release product the chances of FDA asking for a repeat bioequivalence study was low. So that's why we considered the risks to be low for a repeat bioequivalence study request from the FDA.

MR. CASEY: Could you pull up document DX-160.

Q. Doctor, on the screen there, if you can see in front of you, there is Defendant's Exhibit DX-160. Do you see that?

A. Yes.

Q. Are you familiar with this document? Take a minute to read it yes.

A. It's an e-mail from Manish Shah.

Q. You're familiar with this?
A. Yes.
Q. The e-mail about a third of the way down the page, you're cc'd on that e-mail from Mr. Shah, is that correct?
A. Yes.
Q. You've seen this before?
A. I'm sure I must have seen it before.
MR. CASEY: Your Honor, the defendant would offer in DX-160 in evidence.
THE COURT: Received.
(Defendant's Exhibit 160 received in evidence)
Q. Dr. Mukhopadhyay, I want to direct your attention -- first there is a top e-mail from Srinivasa Rao, if I pronounce that correctly?
A. Yes.
Q. Is that she?
A. It's a he.
Q. According to this document, he was the vice-president and head of regulatory affairs, North America Generics for Dr. Reddy's Laboratories, correct?
A. Yes.
Q. The e-mail below that is from Manish Shah, as you mentioned. Who is Manish Shah?
A. He's the CEO of Cerovene.
Q. It's sent to an Alok Sonig at Dr. Reddy's?

A. Yes.

Q. You are copied along with Mr. Rao and a Ray DiFalco at Cerovene, correct?

A. Yes.

Q. The e-mail from Mr. Shah says: Hi, Alok, Cerovene -- this is dated January 6, 2018, correct?

A. Yes.

Q. It says: Cerovene received a complete response letter for pyrimethamine product on December 28, 2017, and the major point in the letter is to repeat BE study using fresh tablets manufactured from RL Fine chem versus unexpired Daraprim tablets. The original BE study involved Ipca's API. FDA has determined that new BE study is required due to the quality issues at Ipca's facility.

Do you see that?

A. Yes.

Q. Then it goes on to say: Cerovene is aggressively pursuing multiple steps to achieve the successful approval and they, as below -- the next page -- there are a number of steps. I direct your attention to step 3. It says purchase five bottles of Daraprim tablets this week, $130,000 per bottle. Do you see that?

A. Yes.

Q. I am going to direct your attention to the next page. This is an earlier e-mail, the December 1 e-mail where Mr. Rao

addresses this to Manish Shah at Cerovene. He says: Hi, Manish. As discussed with you this morning, it is important to plan for a bio-study ASAP using the same CRO in our ANDA as a backup. He goes on to say: With the drug product discipline also not adequate, in my opinion, it is very likely the agency would ask for a new bio study, as they may not accept the bio study conducted using Ipca material.

Do you see that?

A. Yes.

Q. If you turn to the next page -- I'm sorry. I moved too fast.

I want to direct your attention to continue on that e-mail to the sentence that begins: I was under the impression. It's a little further down.

Do you see that where it says: I was under the impression that Cerovene had already received clearance from the FDA RPM to refer the old bio. Very disappointing to run a bio now. We could have done this as a backup.

Do you see that?

A. Yes.

Q. Do you remember being asked about this at your deposition?

A. I don't specifically remember.

MR. CASEY: Why don't we go to --

THE COURT: Why don't you just ask the question that you want answered.

Q. This is an e-mail from Mr. Rao on December 1, 2017 where he says he was under the impression that Cerovene had already received clearance from the FDA. What was your impression of what Mr. Rao was saying in that e-mail?
A. Specific to the sentence?
Q. Yes.
A. He seemed to think that Cerovene had received some kind of clearance from FDA project manager to used the old bio study.
Q. What was your impression of what he meant by saying we could have done this as a backup?
A. That we could run the bio study.
Q. What was your impression of when, like the time frame of when he was referring to?
A. Like maybe post signing the deal at some point.
Q. Signing which deal?
A. The April -- or the January deal.
Q. January deal with Cerovene?
A. Yes.
Q. The backup would have been backup bioequivalency testing in the event that the FDA may have thrown out the old BE results?
A. Yes.
Q. There was some risk?
A. Yes.
Q. That risk was in April, perhaps, when you filed the complete response?

A. Yes.
Q. And, perhaps, back into January when you did the agreement with Cerovene?
A. Yes.
Q. But you didn't do a repeat bioequivalency testing at that point, correct?
A. Yes.
Q. So you waited until the FDA notified you in late December of 2017 that you had to do the new BE testing, correct?
A. Yes.
Q. If you had been aware of this risk back in January or April, you would have advised Cerovene to do the new bioequivalency testing as a backup, correct?
A. Again, it depends on the extent of risk. But if they are reclassified as a high risk, high probability situation or a low risk, it involved significant investment. As you can see, it's $130,000 a bottle. So five bottles, it will be $650,000. So it's a significant investment. We were already paying Cerovene significant milestones for the deal. So on top of that, spending another $650,000 for a bio study which may or may not be requested by the FDA would have been difficult.
THE COURT: Would have been --
THE WITNESS: A difficult choice to make for us.
THE COURT: Would have been --
THE WITNESS: A difficult choice for us.

THE COURT: Thank you.

Q. Understood, Doctor. But my question is, if Dr. Reddy's had been aware of this risk in April of 2017, they would have advised Cerovene to do new bioequivalency testing, correct?

A. If FDA informed us in February or in April that a bioequivalency study would be required, we would have done that.

Q. That's not my question, Doctor. I am saying, the FDA did not notify Dr. Reddy's until December, correct?

A. Yes.

Q. I believe you testified that there was some risk prior to December that they might, correct?

A. Yes.

Q. And my question was, if Dr. Reddy's had been aware of this risk, it would have advised Cerovene to do new BE testing as a backup, correct?

A. So Dr. Reddy's was always aware that there might be a low risk of something like this happening because any submission you make to the FDA, they may come back and ask for an advisory. It's not that Dr. Reddy's was not aware of any risk.

Q. I'd like to go your deposition, Doctor.

MR. CASEY: Could you pull it up, please. At page 266, lines 12 to 16.

Q. Doctor, do you remember having your deposition taken in this case?

A. Yes.
Q. You swore an oath to tell the truth at that deposition?
A. Yes.
Q. The same one you took today, correct?
A. Um-hum.
Q. All of your answers at the deposition were true and correct, correct?
A. Yes.
Q. That deposition was February 12, 2021, correct?
A. Yes.
Q. You were asked about this risk. You were asked: If Dr. Reddy's had been aware of that risk, would it have advised Cerovene to go ahead and do the bioequivalence study? You answered yes. Do you see that?
A. Yes.
Q. And there was nothing preventing Cerovene from doing new bioequivalence testing in April 2017 using RL Fine's API except the cost of finding new RLD and doing the bioequivalence, correct?
A. Correct.
Q. I want to move to another topic now. I want to talk about your efforts to assist Cerovene with sourcing RLD. OK?
A. Yes.
Q. I am going to direct you now back to your direct testimony back at paragraph 26. You state: As Cerovene's point of

contact at Dr. Reddy's, I was included on e-mails related to RLD sourcing, and I connected Cerovene with members of Dr. Reddy's' sourcing team who had relationships with RLD suppliers that might have helped Cerovene.

That was your testimony, correct?

A. Yes.

Q. I want to focus on that phrase, might have helped Cerovene. OK.

In fact, Dr. Reddy's suggested to Cerovene that Cerovene allowed Dr. Reddy's to use its contacts to get RLD more quickly, right?

A. Yes.

Q. In paragraph 27, you write or you testify: Initially, Cerovene had tried to obtain RLD from Espee. I was copied on e-mail communications concerning these sourcing efforts. Cerovene had approved an order to purchase RLD from Espee on December 30, 2017.

That was your testimony in paragraph 27, correct?

A. Yes.

Q. In February 2018, moving up to February 2018, you urged Cerovene to cancel its contract with Espee and work with ProSupplier to source RLD, correct?

A. Yes.

Q. In fact, it was February 12, 2018 when your team identified ProSupplier as a source for Daraprim RLD and notified Cerovene

about ProSupplier, correct?
A. Yes.
Q. It was the prior Thursday, which is February 8, 2018, when one of your team members left a voice mail message for Manish Shah at Cerovene notifying him that ProSupplier was available to source RLD, correct?
A. I am not sure about the voice mail.
Q. Does that time frame sound right to you?
A. Yes.
Q. February 8, 2018?
A. Time frame -- I am not sure of the date, but yes.
Q. As of February 8 of 2018, Dr. Reddy's had identified ProSupplier as a potential source of RLD, correct?
A. Yes.
Q. You communicated that to Cerovene, correct?
A. Not me personally, but yes.
Q. And you suspected that the RLD suppliers were not taking Cerovene's orders seriously because Cerovene was a smaller company than Dr. Reddy's, correct?
A. Yes.
Q. And you believed that if Dr. Reddy's worked with Cerovene to make the purchase orders that Dr. Reddy's could use its relationships to help Cerovene obtain the RLD, correct?
A. Yes.
Q. In fact, you said at the time "we may have a better chance

of getting the RLD quickly if Dr. Reddy's orders on behalf of Cerovene." Do you remember saying that?

A. Yes.

Q. But at that time, February of 2018, Cerovene was attempting to get RLD through a company called Reliant Specialty LLC, correct?

A. Yes.

Q. And you wanted Cerovene to source RLD through ProSupplier instead of Reliant, correct?

A. Dr. Reddy's connected Cerovene with both Reliant and ProSupplier. I think -- I'm trying to remember. Because both Reliant and ProSupplier were through Dr. Reddy's' contact. I believe at one point we decided to go with Reliant versus ProSupplier because Reliant was a U.S.-based company, and we had previous relationships with Reliant, and I was familiar with them. I think they had said they would be able to source the bottles sooner than what ProSupplier had said. That's when Cerovene started bottling it up, start talking to them for the supply.

Q. Doctor, I am just referring to February of 2018, at that point.

A. Let me check.

Q. At that point you wanted ProSupplier to be the sourcing company rather than Reliant, correct?

A. Yes. I believe initially I proposed working with

ProSupplier.

Q. Do you remember saying in an e-mail to one of your colleagues: I believe we work with ProSupplier. We cannot sit and wait for Cerovene to get it. They have tried and failed and are getting delayed.

Do you remember saying that?

A. Yes.

Q. But Cerovene did not take your advice in February of 2018, correct?

A. Yes.

Q. And it was ProSupplier that eventually ended up supplying the RLD, but it wasn't until seven months later, right?

A. Yes.

Q. In fact, the order to ProSupplier was not even placed until late September 2018, correct?

A. Yes.

Q. And you don't have any basis to believe that if Dr. Reddy's from Cerovene had placed an order with ProSupplier for Daraprim RLD in February 2018 that ProSupplier could not have provided the RLD at that time, correct?

A. Yes.

Q. I'll move on.

I want to go back to paragraph 29 of your direct testimony where you testified both ProSupplier and Reliant required advance payment. In my experience, this requirement

was unusual, as payments for RLD are usually made after the product is delivered. At the time I believed it would have been an unreasonable risk to pay both suppliers at the same time due to the amount of money involved and the uncertainty that either company could actually source the RLD.

That is your testimony at paragraph 29, correct?

A. Yes.

Q. Now, on February 23 of 2018, Dr. Reddy's placed an order with Reliant for five bottles of Daraprim, correct?

A. Yes.

Q. But Dr. Reddy's didn't release the funds to Reliant for the order, which was $550,000, until more than five weeks later, on March 28, 2021, correct?

A. I am not sure of the date, but could be.

Q. If you go to your written direct testimony, paragraph 30, please.

Do you see the third sentence there: On March 28, 2018, Dr. Reddy's released to Reliant a prepayment amount of $550,000 for five bottles, the total amount of the order.

You see that?

A. Yes.

Q. So there was about five weeks between the placing of the order and releasing the funds to Reliant, correct?

A. Yes.

Q. Although you testified that paying both suppliers was an

unreasonable risk, that is exactly what Dr. Reddy's did a few months later in September 2018, correct?

A. Yes.

Q. At that time you had two deposits outstanding, one to Reliant and one to ProSupplier, and your team decided to take the very risk that you said you were concerned about in February, correct?

A. Yes.

Q. And you have no basis to believe that if Dr. Reddy's and Cerovene had placed an order with ProSupplier in February 2018 that ProSupplier would not have been able to supply the RLD, correct?

A. Yes.

Q. So the order was placed with Reliant. Five weeks later there was a prepayment for the order. And then several months went by and Reliant was unable to deliver on its promise to source the RLD, correct?

A. Yes.

Q. Finally, in July 2018, Reliant was able to provide one bottle of Daraprim RLD, correct?

A. Yes.

Q. Despite the fact that Reliant was unable to deliver on its promise and source Daraprim RLD for several months in the spring and summer of 2018, you stuck with Reliant, correct?

A. Yes.

Q. As you stated in your direct testimony, instead of engaging ProSupplier, my team and I decided to continue working with Reliant at this time.

That's your testimony at paragraph 33, correct?

A. Yes.

Q. Now, at paragraph 35 of your testimony you state that by August 23, 2018, I updated Dr. Reddy's' management on continuing issues procuring Daraprim RLD from Reliant and a new plan to order additional bottles of RLD from ProSupplier. I then monitored and participated in later e-mails relating to efforts to source RLD through ProSupplier.

That is your testimony, correct?

A. Yes.

Q. In the next paragraph, under paragraph 36, you state that: By September 28, 2018, Cerovene and Dr. Reddy's agreed to place an order with ProSupplier for three bottles while also keeping its existing order with Reliant open. Due to the significant delays in sourcing RLD, Dr. Reddy's executives, in conjunction with Manish Shah at Cerovene, then concluded that we needed to accept the risk of repaying in advance with two different RLD suppliers. Dr. Reddy's paid 50 percent of $375,000 in advance for this order, with the remaining balance to be paid after delivery.

That is your testimony, right?

A. Yes.

Q. Then in paragraph 37, last paragraph I am going to read. 37 says: On November 19, 2018, I informed Dr. Reddy's' executives and other personnel working on the generic Daraprim project that Cerovene had obtained three bottles from ProSupplier. After receiving the three bottles from ProSupplier, the Reliant order was cancelled. Because the ProSupplier bottles were from a different manufacturing lot than the bottle previously sourced by Reliant, Cerovene could not combine the ProSupplier bottles and the Reliant bottle for bioequivalence testing.

That's your testimony, right?

A. Yes.

Q. Doctor, at this time, in 2018, you understood that the FDA required a generic company to have five bottles of Daraprim RLD in order to conduct bioequivalence testing, correct?

A. When you say at this time, this is November 2018?

Q. In 2018.

A. Yes. Earlier in 2018, we knew -- we understood we required five bottles.

Q. You understood throughout 2018 that that was a requirement, correct?

A. Yes. I wouldn't say throughout. At some point during 2018, when Cerovene received this communication from the FDA with the waiver for three bottles.

(Continued on next page)

BY MR. CASEY:

Q. I'm sorry, can you explain?

A. So sometime during 2018, Cerovene had petitioned the FDA for a waiver to use fewer bottles. So I don't remember exactly what date it was, but sometime during 2018, we knew that three bottles would be sufficient.

Q. You're saying sometime in 2018, you understood the FDA granted the waiver?

A. Yes.

Q. I'd like to just go over in more detail the timeline of these paragraphs — 35, 36, and 37.

MR. CASEY: If you can just go back to 35, please, for a second.

Q. You talked about a new plan to order additional bottles of RLD from ProSupplier.

You used the word "additional," there but just so we're clear, as of August 23rd, 2018, you had not yet ordered any bottles from ProSupplier, correct?

A. Yes.

Q. So the "additional" isn't additional bottles from ProSupplier?

A. It's not additional from ProSupplier, it's additional to the one bottle that we had from Reliant.

Q. From Reliant?

A. Yes.

Q. Okay.

So then what happened was another five weeks went by, until September 28, 2018, when Cerovene and Dr. Reddy's finally agreed to place an order with ProSupplier for three bottles of Daraprim RLD rather than five, correct?

A. Yes.

Q. And it was Dr. Reddy's, not Cerovene, that placed that order, correct?

A. Yes.

Q. And you don't remember what the date was that the FDA granted the waiver for three bottles rather than five?

A. I don't remember, but I would assume by this time, we knew that three bottles would be sufficient. That's why we ordered three bottles.

Q. Now, if the FDA had not granted the waiver at the time, you would have ordered five bottles rather than three, correct?

A. Yes.

MR. CASEY: Would you pull up document DX 168, please.

Q. Doctor, on the screen, you'll see Document DX 168. It's an email from Mallikarjun Reddy?

A. Yes.

Q. To a number of people, including you, correct?

A. Yes.

Q. You recognize that document?

A. Yes.

MR. CASEY: Your Honor, the defense would move in DX 168.

MS. HUBINGER: No objection.

THE COURT: Received.

(Defendant's Exhibit 168 received in evidence)

BY MR. CASEY:

Q. Doctor, is this the new plan that you talked about in your affidavit, your written direct testimony, the number of items that are listed?

A. Yes.

Q. So just so we're clear on what the plan was, it says, "We will insist" -- and this, again, is from Mr. Reddy to a number of people within Dr. Reddy's, correct?

A. Yes.

Q. And also Manish Shah, who was the CEO of Cerovene, correct?

A. Yes.

Q. The subject is "Daraprim RLD." It says, "Dear all: As per our/my discussion with Manish on 17 September, we have agreed to go ahead and place order for three bottles with new vendor (ProSupplier) considering below."

Do you see that?

A. Yes.

Q. And Manish is Manish Shah?

A. Yes.

Q. It goes on to say, "We will insist ProSupplier to supply

two bottles from Lot No. AF6966G, as we already have one bottle from this lot. In case if they are not able to source this lot, we will proceed to buy three bottles from new lot."

So what was your understanding of what was being communicated there?

A. So my understanding was we had one bottle from Reliant, which was from this lot number that's here, and we needed three bottles, in total. So their first attempt would be to get two bottles from the same lot, if they could, from ProSupplier; if not, they would go ahead and buy three additional bottles from the same lot or another lot.

Q. That's because the FDA required that the five bottles all come from the same lot, correct?

A. FDA requires five bottles comes from the same lot, but, I believe, as I said earlier, at this point, we knew that we needed only three bottles.

Q. The next line says, "DRL team," and that's Dr. Reddy's?

A. Yes.

Q. "DRL team will negotiate with ProSupplier to agree for a 50 percent advance payment against the order and balance 50 percent when the product is shipped. PO to be placed accordingly."

Is PO purchase order?

A. Yes.

Q. It goes on to say, "We will insist both the vendors, i.e.,

Reliant and ProSupplier, to promptly inform us ahead of time when they get firm visibility to get the product shipped from their primary source so that we don't end up having product from both the suppliers. We will keep a track on this," correct?

A. Yes.

Q. What was your impression of what was being communicated in that bullet?

A. My impression is we had outstanding POs with both suppliers, and we didn't want to be in a situation where we ended up with bottles from both suppliers and ended up being both suppliers for the bottles, like more bottles than we needed.

Q. The last bullet there says, "When one supplier is able to deliver the product, we will take refund from the other. This way, we increase chances of having product soon."

Do you see that?

A. Yes.

Q. What was your impression of what was being communicated in that bullet?

A. We had -- we were trying to derisk by having two suppliers, try to source the bottles.

Q. Did you say "derisk"?

A. Yes.

Q. What do you mean by that?

A. Like, if one doesn't give us the bottle, the other one could, potentially.
Q. You wanted to get a refund from the company that --
A. Does not give us.
Q. The bottles that you don't need, you want to get a refund for that, correct?
A. We want a refund for the company that is unable to source the bottles or whoever is not -- unable to source the bottles earlier.
Q. Now, just to go, again, on timing, this email is September 19th of 2018, correct?
A. Yes.
Q. So from that time -- well, let me back up.

It was November 19 of 2018. As you state in paragraph 37, November 19 is when you informed the Dr. Reddy's team that Cerovene had obtained the bottles, correct?
A. Yes.
Q. I just want to focus on that period of time, that September 19, the date of this email, when the new plan was explained from Mr. Reddy and the time that you actually got the bottles. Okay?
A. Yes.
Q. It was not until October 17, 2018, that Dr. Reddy's released to ProSupplier the advance payment for the three bottles it had ordered, correct?

A. I don't have the date with me, but, you know, it could be correct.

Q. Maybe I can show you a document to refresh your recollection.

MR. CASEY: Can we pull up GX 3390, please.

Q. Do you see GX 3390, Doctor?

A. Yes.

Q. Are you familiar with this? It's a rather long email chain. Are you familiar with this?

A. Yes.

Q. In the top email, there is -- this is the email, it appears, you were referencing Monday, November 19, 2018, from Mr. Reddy to you and a number of others, and the email reads, "Good to know the product is received. Thank you."

Do you see that?

A. Yes.

Q. If we could just work backwards on this document and go to the last page of the document, these emails were produced in this form on page 16 and 17. This is the earliest in time email from -- at the bottom of 16 — that one there — from Ramesh Rachapudi, September 21, 2018, and the next page, here's the PO.

Do you see that?

A. Yes.

Q. Is that the purchase order for the --

A. Yes.
Q. -- bottles from ProSupplier?
A. Yes.
Q. So that was on September 19 -- well, September 21st, rather, sorry. September 21st, 2018, was the purchase order date, correct?
A. Yes.
Q. The next email up, on that page 16, is an email from a Mr. Koteswar Rao. It says, "Dear Ramesh: PO has been shared with vendor."

Is the vendor ProSupplier?

A. Yes.
Q. "We have instructed vendor all the points which we have discussed before PO, so kindly release the 50 percent advance to vendor."

Do you see that?

A. Yes.
Q. And then moving forward again in time up the email chain, there's a number of emails that I'm not going to ask you about, but if we just go up in time --

MR. CASEY: Up to page 9, please, 009.

Q. -- that email there, from Surendra Chirra at Dr. Reddy's, do you see that.
A. Yes.
Q. And, Doctor, are all these people that are on this email

chain, are they all Dr. Reddy's employees?

A. Yes.

Q. And this is now October 11, 2018. He says, "Did we pay the vendor?"

So as of October 11, 2018, he's asking whether the vendor has been paid, correct?

A. Yes.

Q. And then if you move up again, to page 007, there's an email from someone VV Parsuram, 29 October, 2018, and it says, "Where are we on this?"

Do you see that?

A. Yes.

Q. Then there's a response on the next page up from Mr. Reddy. It says, "Payment made to vendor on 17 October. Update from vendor on lot availability expected this week."

Do you see that?

A. Yes.

Q. So it was not until October 17 that Dr. Reddy's released the advance payment to ProSupplier for the three bottles it had ordered, correct?

A. Yes.

Q. And then moving further up again, to page 002 -- well, the email I want to ask you about is -- I'm sorry, the one on, yes, November 16, 2018.

Do you see that?

A. Yes.

Q. "Three bottles shipped and expected to reach Cerovene by Monday. Please inform them and ask for confirmation on delivery."

Do you see that?

A. Yes.

Q. So ProSupplier actually delivered the bottles on November 16, 2018, about a month from the initial payment, correct?

A. Yes.

Q. And you have no basis to believe that if Cerovene or Dr. Reddy's had ordered five bottles instead of three in September 2018, that ProSupplier could not have provided the five bottles, correct?

A. Yes.

Q. Doctor, I'm going to move to another topic now and talk about Dr. Reddy's engagement of Navigant to assist Dr. Reddy's in assessing the generic Daraprim market.

Dr. Reddy's did employ Navigant to consult and advise Dr. Reddy's on that; is that right?

A. Yes.

Q. In your direct testimony, at paragraph --

MR. CASEY: Can you put that up again, Justin?

Q. -- at paragraphs 13 and 14, you state in paragraph 13, "Third, in assessing the market opportunity, I did not consider

the availability of Bactrim on the market or its pricing. I did not consider Bactrim to be relevant to my assessment because Bactrim is not AB rated to Daraprim, and thus cannot be automatically substituted by a pharmacist for Daraprim. I did not consider the price of Bactrim in my analysis."

That's your testimony at paragraph 13, correct?

A. Yes.

Q. But in assessing the pyrimethamine market, Navigant actually considered the availability of compounded pyrimethamine, correct?

MS. HUBINGER: Objection; lacks foundation.

THE COURT: I didn't hear you.

MS. HUBINGER: I'm sorry. It lacks foundation.

MR. CASEY: Your Honor, I'll withdraw the question. I need to go to the next paragraph. The objection is well-founded.

Just go to paragraph 14.

BY MR. CASEY:

Q. You say, "Similarly, I did not consider the availability of compounded pyrimethamine, or its price, on my pricing projections for generic Daraprim. Compounded pyrimethamine is not automatically substitutable for Daraprim by a pharmacy. Moreover, because compounded drug products are not FDA approved, safety concerns could arise."

That's your testimony in paragraph 14, correct?

A. Yes.
Q. Now the question is: In assessing the pyrimethamine market, Navigant considered the availability of compounded pyrimethamine, correct?
MS. HUBINGER: Again, objection. I don't know whether Dr.Mukhopadhyay has seen this Navigant --
THE COURT: If you don't know, just say I don't know.
THE WITNESS: Yeah, I don't know.
BY MR. CASEY:
Q. I direct your attention to your deposition.
MR. CASEY: If you could pull the deposition up, please, at page 230?
Q. So at paragraph -- or page 230, paragraph 19, you were asked:
"Q. Based on this presentation, the availability of compounded pyrimethamine is something that Navigant considered in making its pricing recommendations?"
MS. HUBINGER: Again, objection, your Honor.
THE COURT: Sustained.
Q. And Navigant identified compounded pyrimethamine as a competing product that was being used to replace Daraprim, correct?
MS. HUBINGER: Again, objection.
THE COURT: Sustained.
Just say objection.

Sustained.

BY MR. CASEY:

Q. Now, in assessing the market opportunity for generic Daraprim, you understood that Daraprim sales had fallen from around 1 million tablets per year to about 150,000 after the price increase in 2015, correct?

A. Yes, based on the analysis that I did.

Q. Some of those Daraprim patients switched to compounded pyrimethamine, correct?

A. Potentially, yes.

Q. Did you say "potentially"?

A. Yes.

Q. Some of them -- some of the patients actually did switch to compounded pyrimethamine, correct?

THE COURT: You're asking for this witness' knowledge?

MR. CASEY: Yes.

THE COURT: Do you know whether patients switched to compounded pyrimethamine?

THE WITNESS: I don't have a personal knowledge, but I would assume, yes.

BY MR. CASEY:

Q. In fact, Dr. Reddy's hoped to be able to capture some of the sales that went to compounded products, correct?

A. Yes.

Q. Doctor, I have no --

A. Sorry. I would -- I don't think Dr. Reddy's expected to convert some of the patients that went to compounded product, and this goes back to the fact that the compounded product was being sold very cheap. I think we had one customer even tell us that they would not be sourcing the Daraprim's generic product from Dr. Reddy's.

Q. I'm sorry, you had one customer tell you that they would not be sourcing Daraprim's generic product from Dr. Reddy's. Could you explain that?

A. Yes. Because they were using the compounded product.

Q. And Dr. Reddy's hoped to be able to capture some of the sales that went to compounded products, correct?

A. Hoped, yes.

MR. CASEY: Doctor, that's all I have. Thank you very much.

MS. HUBINGER: Thank you, your Honor. I have a few questions for redirect.

REDIRECT EXAMINATION

BY MS. HUBINGER:

Q. Good afternoon, Dr.Mukhopadhyay. Can you hear me okay?

A. Yes.

Good afternoon.

THE COURT: You can remove your mask.

MS. HUBINGER: I'm sorry. I was just told that. Thank you.

BY MS. HUBINGER:

Q. So I'd like to pick up right where the defendants left off.

You were talking about a customer that you said was not interested in a generic Daraprim product because it was using a compounded version; is that correct?

A. Yes.

Q. Besides that one customer, did you reach out to any other customers to see whether they would be interested in generic pyrimethamine product?

A. Yes.

Q. How many?

A. I think we reached out to all the major wholesalers and retailers. I don't remember how many, but all the ones that we thought could source Daraprim.

Q. Do you have, like, a rough range of how many that might be?

A. So there are three major wholesalers. I believe we reached out to all three of them.

Q. Of the other ones, were any of the others uninterested in a generic version of Daraprim because they used compounded?

A. From what I remember, only one customer told us that. I think it was Econdisc that told us — Econdisc, E-c-o-n-d-i-s-c — that they were not interested because they were sourcing the compounded product.

Q. But the other customers you spoke to, were they interested in a generic pyrimethamine product?

A. So I'm trying to remember. I think some of the customers said they were selling the branded one because that was the only one available. Some of them said, after the price increase, they were not sourcing the Daraprim anymore.

Q. So, currently, Dr. Reddy's generic product is on the market, right?

A. Yes.

Q. Do you currently sell your generic pyrimethamine product to some of those customers you spoke with?

A. Yes.

Q. How many of them do you sell to?

A. I think -- I don't know off the top of my head. I believe we sell to the major wholesalers, plus there are smaller customers that we sell to.

Q. Understood.

THE COURT: So, Dr.Mukhopadhyay, I think I lost the chain of questioning here.

Did I understand you to say that, at some point, before you went on the market with your generic product --

THE WITNESS: Yes.

THE COURT: -- that competes with the brand Daraprim --

THE WITNESS: Yes.

THE COURT: -- you called certain customers?

THE WITNESS: Yes.

THE COURT: Did I understand that correctly?

THE WITNESS: Yes.

THE COURT: And you asked those customers, if we put a generic version of Daraprim pyrimethamine on the market, would you be interested?

THE WITNESS: Yes.

THE COURT: That's what you did?

THE WITNESS: Yes.

THE COURT: And what did you learn from those conversations?

THE WITNESS: So from those conversations, at least one customer told us that they were using the compounded version, so they were not interested -- or they were not that excited about the ANDA product.

THE COURT: And I think this attorney asked about the other conversations.

THE WITNESS: Yes. The other conversations -- so maybe I'll give a little bit of context of why we reached out.

So we had looked at Daraprim numbers or the usage numbers from IQVIA, and the numbers had dropped -- after Vyera, or Turing at this point, when they bought the product, the numbers had dropped significantly, so we weren't sure what the usage of the product was.

So we had reached out to all customers to see if they were interested, were they using the brand Daraprim. And

that's how we got to know some of them said we were using the compounded Daraprim, and that one customer had said we are using compounded, so we assume they would not be that interested in buying the ANDA product. The other customers, some of them said they stopped using Daraprim, some of them said they were still using Daraprim.

So, yes, some of them are using, some of them are not using.

THE COURT: I thought you were asked did you inquire of them, these customers, whether they would be interested in a generic pyrimethamine.

Did you or didn't you ask?

THE WITNESS: I think the question was more of what were they using --

THE COURT: Aha.

THE WITNESS: -- at that point.

THE COURT: So you wanted to know their current practice?

THE WITNESS: Yes.

THE COURT: Not what they'd be interested in in the future?

THE WITNESS: Future.

THE COURT: Thank you. Thank you for clearing that up for me. Thank you.

Counsel.

MS. HUBINGER: Yes, thank you.

BY MS. HUBINGER:

Q. Based on the response of those customers, you ultimately decided to pursue a generic Daraprim project?

A. Yes.

Q. Currently, today, you sell to the major wholesalers?

A. Yes.

Q. Okay. Thank you.

So I'd like to shift gears and talk about the RLD sourcing that you spoke with defendants earlier about.

Do you recall that conversation, about serving in Dr. Reddy's efforts to source Daraprim RLD?

A. Yes.

Q. Just to orient ourselves again in that timeline, I'd like to start at the beginning of the relationship with Reliant. And I believe we established that the first order was made in February of 2018; is that right?

A. Yes.

Q. Before placing that order with Reliant, had Dr. Reddy's been involved with sourcing Daraprim RLD?

A. No.

Q. Who had been --

A. Cerovene.

Q. And why did Dr. Reddy's decide to get involved helping Cerovene source Daraprim RLD?

A. So I believe Cerovene had spent probably a month or more trying to source it from this company named S.P., and they were unable to source it.

Q. Did a month seem like a long time to you for sourcing Daraprim RLD?

A. Yes. Because not only they were unable to source, I don't think they received an answer from S.P. that they will be able to source.

Q. Was it unusual for Dr. Reddy's to get involved in sourcing RLD for one of their in-licensing partners, like Cerovene?

A. Yes.

Q. Why is that unusual?

A. So the partnership was structured such that Cerovene would take all responsibilities for development all the way to getting the ANDA approved, and Dr. Reddy's would be more responsible for the commercialization and marketing of the product. So, given that arrangement, it is unusual that we would help them for development activities with the sourcing RLD.

Q. One way you helped Cerovene was introducing them to Dr. Reddy's contacts, and you mentioned, I think, when you were discussing it with Mr. Casey, that both Reliant and ProSupplier were Dr. Reddy's contacts?

A. Yes.

Q. And in February 2018, were you choosing between ordering

from ProSupplier and ordering from Reliant?
A. Yes.
Q. Was it your suggestion that Dr. Reddy's choose Reliant?
A. Yes.
Q. And why did you make that suggestion?
A. I believe, at that point, ProSupplier had said -- I don't remember the exact number of weeks; ProSupplier had probably said, like, six weeks, Reliant said three weeks. And I knew Reliant because we had worked with them in the U.S. and they were based in the U.S. and they set shorter timeline, so we went with Reliant.
Q. So it was your suggestion at Dr. Reddy's to pursue a purchase order with Reliant?
A. Yes.
Q. And that is ultimately what you did in February 2018?
A. Yes.
Q. And in February 2018, how many bottles did you order from Reliant?
A. Five bottles, I believe.
Q. And did you have to prepay for those?
A. Yes.
Q. Do you recall about how much you had to prepay?
A. I think it must have been $375,000.
Q. If you had chosen to source from ProSupplier in February 2018 instead of Reliant, would you have had to prepay

for those five bottles as well?
A. Yes.
Q. And, at that point — we're in February 2018 — the beginning of Dr. Reddy's involvement, the search for Daraprim RLD, why didn't you choose to source from both ProSupplier and Reliant at the same time?
A. It was a significant amount of money, and given Cerovene already had issues trying to source from one company, we didn't want to start paying two companies for RLD which we didn't know whether they would be able to source.
Q. When you initially ordered five bottles of Daraprim RLD from Reliant in February 2018, how long did you expect it to take to get those five bottles?
A. I think they had said it was going to be three or four weeks. I don't remember the exact timeline, but they had said in an email to Mallikarjun, or the Dr. Reddy's contact, that they would be able to source within I believe it was three or four weeks. I don't remember the exact...
Q. But I recall you talking with Mr. Casey that they were only able to deliver one bottle in July of 2018; is that right?
A. Yes.
Q. At any point before they delivered that one bottle, did you consider switching?
A. Yes.
Q. And who did you consider switching to?

A. ProSupplier.
Q. Did you ultimately decide to continue sourcing from Reliant?
A. Yes.
Q. Why?
A. I believe Reliant communicated to -- and this was, again, I heard it through Manish, that ProSupplier was trying to source the bottles through Reliant, so we believed that they didn't have an independent source.
Q. After Reliant delivered that one bottle, in July of 2018, you eventually decided, in September, to place a purchase order with ProSupplier; is that right?
A. Yes.
Q. And that purchase order was for three bottles?
A. Yes.
Q. And at that time, you had both a purchase order with ProSupplier and a purchase order with Reliant open?
MR. CASEY: Your Honor, objection; she's leading the witness.
THE COURT: Sustained.
MS. HUBINGER: Okay, sorry. I'm just trying to reorient ourselves here.
BY MS. HUBINGER:
Q. In September of 2018, who did you have RLD purchase orders open with?

A. I believe we had it with both companies, Reliant and ProSupplier.

Q. Earlier, you testified that there was a financial risk to having both orders.

Why, at that time, did you decide to take the financial risk of placing a purchase order with both companies?

A. So two reasons.

One, a significant time had passed, and we were still not able to source the bottles.

And, second, at that point, we were looking for three bottles versus five bottles, so it was a lower risk from a financial perspective.

Q. Leading up to the September 2018 order with ProSupplier, were you personally communicating with anyone at ProSupplier?

A. No.

Q. Do you know who at Dr. Reddy's or Cerovene would have been in contact with ProSupplier?

A. I would think it was Mallikarjun Reddy or someone from his team.

Q. Would anyone at Cerovene have been involved, too?

A. With ProSupplier? I don't think so.

Q. Okay. Do you know whether or not ProSupplier was able to supply more than three bottles of Daraprim RLD in September 2018?

A. We placed an order for three bottles. We didn't place an

order beyond that, so I don't know. I cannot say one way or the other.

Q. I'd like to jump topics again to something that the defendants covered earlier, and that was your portion of your written direct testimony discussing Cerovene's API supply source. I want to talk a little bit about your due diligence process, when you're evaluating an in-licensing partner.

Were you responsible, in your role at Dr. Reddy's, for doing due diligence on Cerovene when you were considering a project together?

A. Yes.

Q. Was part of that due diligence looking at API supply?

A. So, in general, no, but in the specific case, since Cerovene had a communication from the FDA that their ANDA was not approved because of the API supply, so, yes, we did.

Q. And why, in this particular case, is API important to you?

A. Because the ANDA would not be approved by FDA without API.

Q. As part of your diligence process, did you ask Cerovene about its source for API?

A. Yes.

Q. At the time you signed the memo recommending Cerovene to become a partner of Dr. Reddy's, who was Cerovene's API supplier?

A. So, originally, the API supplier was Ipca, and they had also found RL Fine, which was their substitute supplier.

Q. So at the time you recommended entering a partnership with Cerovene, had they identified an API supplier?
A. Yes; RL Fine.
Q. Was that an important part of your decision to --
A. Yes.
Q. -- recommend them?
A. And that is why we took between March to January to sign the agreement.
Q. As part of your due diligence, did you consider whether RL Fine was a reliable source of API?
A. I wouldn't -- yeah, so we -- because Cerovene was responsible for managing the API source, we did not get into reliability, but we knew that RL Fine was an API supplier based out of India and all the details.
Q. How did you know that?
A. Through Cerovene. But then, of course, we found out RL Fine exists in India, and we did some diligence on the side.
Q. When you say some diligence on the side, what do you mean by that?
A. Like, we knew whether -- it was a lone supplier in India and the API that they were supplying, like, to other countries, so those things we found out.
Q. Did those things impact your decision to recommend a partnership with Cerovene?
A. Yes. We knew that they had -- they were manufacturing the

API for other countries, so we thought they would be reliable.

Q. And before RL Fine, had Cerovene considered any other API suppliers?

A. Yes.

Q. Which one, or others?

A. They had considered Fukuzyu.

Q. If they hadn't been able to use Fukuzyu, would you have considered them a reliable source of API?

A. Yes.

Q. Why?

A. Because they were supplying to the brand.

MS. HUBINGER: Just one moment more.

(Pause)

MS. HUBINGER: I don't think I have any further questions. Thank you very much for your time, Dr. Mukhopadhyay.

THE COURT: Any recross?

MR. CASEY: No recross, your Honor. Thank you.

THE COURT: Thank you.

Thank you very much. You may stand down.

(Witness excused)

THE WITNESS: Thank you.

THE COURT: Next witness.

MR. MEIER: Your Honor, the government calls as its next witness Edward Conroy, who's an expert witness. And for

the government, Mr. Conroy will be handled by my colleague attorney Armine Black.

THE COURT: Mr. Conroy, come on up and take the witness stand, if you would, and remain standing.

EDWARD VINCENT CONROY,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

THE COURT: Please state your full name.

THE WITNESS: Edward Vincent Conroy.

THE COURT: How do you spell your last name?

THE WITNESS: C-o-n-r-o-y.

THE COURT: I think you're about to be shown your affidavit, which is GX 8002. I'm going to ask you, please, to look at the last page of your affidavit, which I think is page 38, and I want to know if you authorized your electronic signature to be put on the last page of the affidavit?

THE WITNESS: Yes, your Honor.

THE COURT: Before you did that, did you read this document with care?

THE WITNESS: Yes, your Honor.

THE COURT: Do you swear to the truth of the statements in it?

THE WITNESS: Yes, your Honor.

THE COURT: Any objection to receipt of 8002?

MR. PARKS: Your Honor, Manly Parks on behalf of the

Defendant Shkreli, and there is no objection.

THE COURT: Thank you.

GX 8002 is received.

(Government's Exhibit 8002 received in evidence)

THE COURT: Cross-examination?

MX. BLACK: Your Honor, before we begin the cross-examination, plaintiff would like to move in two exhibits attached to the affidavit. It's Exhibits GX 7002 and GX 7003. Those are summary exhibits summarizing certain terms of Daraprim distribution contracts.

THE COURT: Any objection?

MR. PARKS: Your Honor, no objection.

THE COURT: They are received.

(Government's Exhibits 7002, 7003 received in evidence)

CROSS-EXAMINATION

BY MR. PARKS:

Q. Good afternoon. My name is Manly Parks. I'm part of the team of attorneys representing Mr. Shkreli in this matter.

Sir, first, let me ask you: Other than this case, have you ever been retained as an expert witness on any topic having to do with pharmaceutical distribution?

A. No.

Q. You have never --

THE COURT: That is a thrilling statement. That is so

unusual, so thank you.

Q. You have never published any articles or other publications related to the distribution of pharmaceuticals, have you?

A. No.

Q. You have not, correct?

A. Correct.

Q. You have never conducted any sort of industry survey related to the distribution of pharmaceuticals, have you?

A. No.

Q. You have not conducted any sort of formal market analysis related to pharmaceutical distribution, have you?

A. No.

Q. Sir, you worked for more than 25 years for the company that owned Daraprim historically, correct?

A. Yes, I worked for Burroughs Wellcome.

Q. And you refer to that company and its corporate successors in your direct testimony, generally, as GSK, correct?

A. Yes. We were acquired by Glaxo. Glaxo then became GlaxoSmithKline.

Q. Sir, when I use the term "GSK," I'm going to adopt the same definition you used for that term in your direct testimony.

Is that okay with you?

A. Yes.

Q. And you will understand, when I'm referring to GSK, I'm referring to that same group of corporate successors?

A. Yes.
Q. In your direct testimony, you discuss your experience at GSK with drug distribution.
During your time with GSK, you never made any recommendations with respect to the distribution of Daraprim, did you?
A. No.
Q. During your time with GSK, you were never tasked with conducting a review of GSK's distribution practices specifically regarding Daraprim, were you?
A. Specifically tasked? No. But as part of drug development and marketing committees, we would discuss the various products at Burroughs Wellcome and Glaxo, whether I was distribution, whether issues that needed to be solved -- so without issues, no particular study was asked for.
THE COURT: So, counsel, I'm going to ask you to move that mic a little bit. Great. Thank you.
MR. PARKS: Is that okay?
THE COURT: Yes. I think there's a little feedback when you're leaning into it.
MR. PARKS: I'm sorry.
THE COURT: So move it where it's comfortable for you.
Good. Thank you.
MR. PARKS: Yes.
BY MR. PARKS:

Q. Sir, by the time you joined GSK, the distribution model for Daraprim had already been established, correct?
A. Pretty much since 1953, I believe.
Q. So you don't have any personal knowledge concerning the reasons that GSK selected that distribution model for Daraprim, do you?
A. When it first started, I was six years old, so, no, sir.
Q. In your direct testimony, you referred to your experience with market research and analysis while you were with GSK?
A. Yes.
Q. During the time you were employed by GSK, you never did any market analysis specifically on Daraprim, did you?
A. Not that I recall.
THE COURT: Okay. So maybe I misidentified the feedback.
THE WITNESS: I'm --
THE COURT: Okay, good. So let's adjust it so it's good for everyone. Thank you.
BY MR. PARKS:
Q. Sir, during your time as an assistant to the marketing services manager at GSK, your duties included being a product planner for certain of GSK's products, correct?
A. Yes.
Q. During the time you were employed by GSK, you were never a product planner for Daraprim, were you?

A. No.
Q. From 1983 to 1988, your responsibilities at GSK related to consumer products, correct?
A. What years, again?
Q. 1983 to 1988.
A. That's approximately right, yes.
Q. During that period of time where your responsibilities at GSK related to consumer products, you did not have any specific responsibilities relating to Daraprim, did you?
A. No.
Q. From 1988 to 1995, or approximately those date ranges, you were a national account trade development manager at GSK, correct?
A. Yes.
Q. During that period, you did not have any specific responsibilities related to Daraprim other than that it was included on the price lists you used with those accounts, correct?
A. Yes. It was in my purview to make a recommendation, monitor, whatever, like any of the other drugs on that price list.
Q. But other than that, you didn't have any other specific responsibilities related to Daraprim during that time, correct?
A. No.
Q. Well, it's incorrect or it's correct?

A. No -- yes, you're correct.
Q. Thank you.
THE COURT: So let's move that mic back.
Good.
THE WITNESS: How's that?
THE COURT: Let's try it there.
BY MR. PARKS:
Q. Sir, during that same period of time, from 1988 to 1995, you have no recollection of any specific conversations regarding Daraprim; is that correct?
A. No specific conversations.
Q. From 1997 through 1998, you were a marketing director for GSK's skincare division, correct?
A. Yes.
Q. During that period of time, you did not have any responsibility for Daraprim, did you?
A. No, but I did get involved in distribution of the skincare products.
Q. From 1998 to 2000, you were a senior district sales manager for GSK, correct?
A. Yes.
Q. During that period, other than the fact that Daraprim was included on price lists you used, you don't recall doing anything specifically related to Daraprim, do you?
A. No.

Q. Your last position with GSK, during the period 2000 to 2001, was as a senior manager of professional healthcare communications, correct?
A. Yes.
Q. During that period, once again, you did not have any specific responsibilities related to Daraprim, did you?
A. No. Daraprim was not what's considered a -- they were not spending marketing dollars to promote the use of Daraprim, so there was nothing -- you know, it was doing so well in the distribution channels, there was no activity needed.
Q. During your time, sir, at GSK, you did not have any personal knowledge of reports of adverse events related to Daraprim because those would have been reported to medical, not to any of the positions you held, correct?
A. Correct, in the fact that I was also on anti-infective -- we launched Retrovir, AZT, during that time period, so I was part of distribution, marketing, medical, production, committees; and if there were issues with any of those drugs, they would have been discussed during those meetings.

And I do not recall any issues with Daraprim, even though Daraprim is commonly used with HIV patients.
Q. Sir, you would agree, wouldn't you, that during your time at GSK, a medical question or concern could have been raised about Daraprim but you simply did not become aware of it because it was not reported to you; isn't that right?

A. Yes, sir.

MR. PARKS: Your Honor, we're at about 5:00 o'clock. I'm about to move beyond the background section. This would be an appropriate time if it's comfortable for your Honor; if not, I can continue with some questions.

THE COURT: No, I think we've all had a nice long day.

Again, this is subject to change. If my consultations lead to different numbers, I'll give you those in the morning. The defendant has pulled ahead of the plaintiffs, and I have seven hours and 17 minutes for the plaintiffs and eight hours and 46 minutes for the defendant.

So we're a little ahead of our five hours a day, which means we're on target. I don't know if you're on target with your witness lists; that's a separate issue. And I wish you all a good evening.

Give me just a moment here to take some materials with me.

Thank you, everyone.

(Adjourned to December 17, 2021 at 9:30 a.m.)

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